NOTICES OF PROPOSED RULEMAKING

Unless exempted by A.R.S. § 41-1995, each agency shall begin the rulemaking process by first filing a Notice of Proposed Rulemaking, containing the preamble and the full text of the rules, with the Secretary of State's Office. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the Arizona Administrative Register.

Under the Administrative Procedure Act (A.R.S. § 41-1001 *et seq.)*, an agency must allow at least 30 days to elapse after the publication of the Notice of Proposed Rulemaking in the *Register* before beginning any proceedings for adoption, amendment, or repeal of any rule. A.R.S. §§ 41-1013 and 41-1022.

NOTICE OF PROPOSED RULEMAKING

TITLE 18. ENVIRONMENTAL QUALITY

CHAPTER 2. DEPARTMENT OF ENVIRONMENTAL QUALITY
AIR POLLUTION CONTROL

PREAMBLE

1. **Sections Affected** — **Rulemaking Action**

R18-2-603	Repeal
Article 15	New Article
R18-2-1501	New Section
R18-2-1502	New Section
R18-2-1503	New Section
R18-2-1504	New Section
R18-2-1505	New Section
R18-2-1506	New Section
R18-2-1507	New Section
R18-2-1508	New Section
R18-2-1509	New Section
R18-2-1510	New Section
R18-2-1511	New Section
R18-2-1512	New Section
R18-2-1513	New Section
R18-2-1514	New Section
R18-2-1515	New Section

2. **The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**

   Authorizing statutes: A.R.S. §§ 49-104(A)(11) and 49-425

   Implementing statute: A.R.S. § 49-501

3. **The name and address of agency personnel with whom persons may communicate regarding the rulemaking:**

   Name: Amy Wainright or Martha Seaman, Rule Development Section

   Address: Department of Environmental Quality
   3033 North Central Avenue
   Phoenix, Arizona 85012-2809

   Telephone: (602) 207-2225 or (602) 207-2222 (Any extension may be reached in-state by dialing (800) 234-5677, and asking for that extension.)

   Fax: (602) 207-2251

4. **An explanation of the rule, including the agency's reasons for initiating the rule:**

   Overview

   The Department of Environmental Quality (ADEQ) is proposing new rules that structure the smoke management process for prescribed forestry and rangeland burns. Prescribed burning is conducted by federal and state land managers (F/SLMs) for many purposes, including the prevention of wildfires and the associated degradation of air quality.

   Prescribed burning of forest and range lands has been defined by the U.S. Environmental Protection Agency (EPA) as: "The controlled application of fire to wildland fuels in either a natural or modified state, under specific environmental conditions which

allow the fire to be confined to a predetermined area and at the same time produce the intensity required to attain planned resource management objectives."

The proposed rules will assist ADEQ and the F/SLMs in managing prescribed burns such that the smoke from multiple burns, or the smoke from a single burn under adverse conditions, does not impact the health of persons living near the burn and does not impact visibility in any smoke-sensitive areas, such as federal Class 1 wilderness areas. These benefits are further described in the Economic Impact Statement.

The EPA has provided guidance on how to develop a prescribed burning program that achieves the above goals and that constitutes Best Available Control Measures (BACM). It is the intent of ADEQ to have such a BACM-level program. As stated in the EPA's Prescribed Burning Technical Information Document (OAQPS, September 1992, EPA 450/2-92-003):

> "The specific steps employed by a state to achieve these objectives constitute the state's 'smoke management plan.' The following are characteristic elements of a more developed smoke management plan:
>
> 1. Registration of acres to be burned in the coming year.
> 2. Designation of burn/no burn days based on a number of specific meteorological factors.
> 3. Allocation procedures to determine how many and which acres will be burned on a given day.
> 4. The specific emission reduction techniques to be used."

The proposed rules follow this outline generally and follow many of the specific suggestions contained in the EPA guidance. ADEQ has had Burn Guidelines ("Interim Operations Guidance for Smoke Management in Arizona", ADEQ 1991) in place for several years. These Guidelines were created jointly between ADEQ and the affected F/SLMs, and they also track the EPA guidance. Each of the F/SLMs in Arizona has complied with the ADEQ Burn Guidelines since the time of their creation up to and including the present time. Most of the provisions in the proposed rule are codifications of the practices currently being followed under the Guidelines and under Arizona's current rule (R18-2-603). However, since guidelines can only invite voluntary participation and since the smoke management program has been successful in reducing the effects of air pollution, ADEQ is proposing to make the program mandatory and is placing it in rule. Section 101 of the federal Clean Air Act Amendments of 1990 directs states to take responsibility for air pollution control with the assistance of the federal agencies. Many of the F/SLMs in Arizona were consulted during the drafting of the rules.

Please note that agricultural burns are not covered here and are not governed by the proposal. Agricultural burning in Arizona, unlike other states, is controlled through a permitting program under 18 A.A.C. 2, Article 6.

Purposes of Prescribed Forestry Burning Programs

Most prescribed burns are thought of as those that occur from planned management ignitions to achieve a particular objective. The term "prescribed burn", however, is also applied to burns that occur as a result of natural ignitions (e.g., from a lightning strike) where the resulting fire is allowed to burn under pre-identified conditions and an approved burn plan to maintain the natural role of fire in the environment.

Prescribed burns may be applied to native or planted domesticated vegetation or to activity-created fuels. Vegetation may be burned to eliminate existing dominant species (stand replacement), control invaded weeds and brush species, maintain the current stand (underburning), or reduce the natural build-up of hazardous fuels. Activity-created fuel is the residue left after some management activity has taken place, such as timber or crop harvest, or land clearing.

Prescribed fire is used to achieve a number of objectives. Among the most cited for wildlands are:

- Hazard reduction
- Site preparation
- Wildlife habitat improvement
- Range improvement
- Disease and insect control
- Ecosystem maintenance

Other objectives cited across the country include management of endangered species, management of competing vegetation, aesthetics improvement, access improvement, and recycle of nutrients. The following paragraphs discuss several of the major objectives of prescribed burning across the country.

Hazard Reduction

In wildlands, fuels can accumulate in amounts sufficient to pose a serious wildfire threat if they are not removed. (A discussion of the various types of forests and their capacity for fuel accumulation can be found in the Arizona Comparative Environmental Risk Project, ADEQ 1995.) Fuels may accumulate naturally or be the result of man-made activities, such as timber harvesting. Prescribed fire is 1 method for removing the accumulation of the fuel. By removing total available fuels, prescribed fire can reduce the damage to an area in which a wildfire occurs and reduce the associated air quality impacts. In addition, by creating "breaks" in fuel

continuity, prescribed fire allows for easier control of a wildfire.

Site Preparation

On some wildlands, the site needs to be prepared for regeneration after harvest. Regeneration may occur through seeding, planting, or natural regeneration. For each method, fire can be used to make regeneration easier.

Wildlife Habitat Improvement

Prescribed fire is used to reduce undesirable plant species, encourage desirable habitat by changing plant composition, reduce vegetation growth, and manage critical habitats. Prescribed fire is used to develop areas for wildlife species to browse, nest, forage, etc. On rangelands, firing techniques are used to promote a mosaic pattern on the landscape encouraging different stages of growth from range species, thus promoting species diversity.

Range (Forage) Improvement

In wildlands and range lands used for forage crops, prescribed burns can increase the availability, palatability, quality, and quantity of grasses and forage material for livestock as well as for wildlife species.

Disease and Insect Control

Under very controlled conditions in wildlands, prescribed burning can be used to control various diseases and insects without destroying the stand.

Ecosystem Maintenance

In many of North America's ecosystems, "natural" fire is a significant ecological process. Many plants have structural adaptations, specialized tissue, or reproductive features that favor them over other species in a fire-dominated environment. The removal or alteration of "natural" fire patterns (e.g., from the attempt to exclude fire) in these ecosystems can significantly change the make-up of the ecosystem. Prescribed burning is used in some areas to maintain those fire-tolerant or fire-dependent species.

Air Emissions

The burning of wildland biomass releases a variety of pollutants into the atmosphere. The majority of these emissions are carbon dioxide, carbon monoxide, hydrocarbons, and particulate matter, with particulate matter having the greatest impact. Because the wood or vegetative matter contain other elements, prescribed burning and wildfires also release other chemical compounds, including toxics, into the atmosphere, though usually in significantly smaller quantities.

"PM10" stands for particulate matter that is smaller than 10 microns. PM10 is an air pollutant that is inhaled and then often trapped in the lungs. The prevention of excess PM10 emissions (from wildfires and from multiple prescribed burns) is an important goal for the proposed rules. The rules recommend management practices that will lessen these PM10 emissions (see proposed rule R18-2-1509).

Most PM10 emissions are generated during the flaming and smoldering stages. Generally, emission rates during the smoldering phase are higher, sometimes significantly higher, than those during the flaming phase. These proposed rules take continued smoldering into account as part of the entire smoke management process.

Weather and Smoke Dispersion

Weather categorization models for prescribed burning programs are based on an assessment of the dispersion capabilities of the atmosphere. The proposed rules use such a model. Poor dispersion limits the amount of burning because under such conditions smoke can accumulate in quantities sufficient to violate ambient air quality standards or other criteria. Sufficiently poor dispersion can result in the disapproval of burn requests. Good or favorable dispersion allows prescribed burning to occur without endangering ambient air quality standards, if the amount of prescribed burning does not "overload" the ability of the atmosphere to disperse the emissions. Thus, even under favorable dispersion conditions, the quantity and location of burning needs to be assessed.

The capability of the atmosphere to disperse smoke from prescribed fires tends to be related to 3 primary factors: atmospheric stability, mixing height, and transport wind speed. These rules incorporate a combination of these factors.

By using the results of a smoke dispersion evaluation, ADEQ can gauge the capacity of the atmosphere on any given day to disperse smoke from prescribed burns so as to avoid violations of the National Ambient Air Quality Standards (NAAQS) for PM10 and to avoid health and environmental impacts. In order to ensure that this capacity is not exceeded, ADEQ must have in place a procedural framework that allows it to identify how much burning is being planned and where it is proposed to occur. This information allows ADEQ to make decisions as to which burns should proceed on any given day. The rules represent such a framework.

Description of Rule, Section-by-Section

ADEQ's proposed rule contains the following Sections:

R18-2-603. ~~Forestry Management~~ (Reserved) -- Repeals current rule.

R18-2-1501. Definitions -- Contains definitions.

R18-2-1502. Applicability -- Limits applicability of the rules to state and federal land managers.

R18-2-1503. Annual Registration for Prescribed Burns -- Requires land managers to register all upcoming prescribed burns by August of each year.

R18-2-1504. Burn Plan Contents -- Requires the details of each burn to be supplied to ADEQ 2 weeks before requesting permission to ignite.

R18-2-1505. Burn Requests and Authorization -- Requires permission to burn each day of the burn and requires ADEQ's response.

R18-2-1506. Smoke Dispersion Evaluation -- Describes how ADEQ will make the determinations of how much burning to allow.

R18-2-1507. Burn Accomplishment; ADEQ Recordkeeping -- Requires that the F/SLMs report the number of acres burned; requires ADEQ to maintain a database of that information.

R18-2-1508. Prescribed Natural Fires (PNFs); Plan; Authorization; Monitoring; Inter-agency Consultation -- Sets out the procedures for prescribed natural fires, completely apart from the procedures for other prescribed burns.

R18-2-1509. Emission Reduction Techniques; Best Management Practices (BMP) -- Lists the control measures for increasing efficiency and reducing air emissions.

R18-2-1510. Monitoring -- Describes mandatory and permissive monitoring of burns.

R18-2-1511. Burner Qualifications -- Requires burns to be conducted by trained personnel.

R18-2-1512. Public Awareness Program -- Describes public education and outreach efforts.

R18-2-1513. Surveillance and Enforcement -- Describes actions that ADEQ may take regarding enforcement.

R18-2-1514. Oversight -- Mandates a report on the F/SLMs' costs and emissions for the previous year's burns.

R18-2-1515. Forms; Electronic Copies; Information Transfers -- Allows for computer, facsimile, and Internet transfers of information between ADEQ and F/SLMs.

Solicitation of Comments

ADEQ is soliciting comment not only on these proposed rules generally, but also on the 2 following questions specifically:

a. In R18-2-1505, the elements of the Daily Burn Request are not new, with the exception of the reporting of wildfires greater than 100 acres. This economic impact is expected to be small since the proposed rule mimics the Wildfire Reporting System currently used by F/SLMs for their own purposes. The information required by the proposed rule is expected to track, for the most part, the information already reported by F/SLMs on Universal Form ICS 209. The only additional information required relates to "potential smoke and air quality impacts" for wildfires. It is not known at this time whether this information can be extrapolated from Universal Form ICS 209 or whether the form will have to be changed. ADEQ is soliciting comment on this point to make the rule workable, as well as on costs associated with this new element.

b. In R18-2-1504(A)(6) modeling is required for burns greater than 250 acres in size, or greater than 50 acres in size if the burn is within 15 miles of a Class I Area, a PM non-attainment area, a carbon monoxide non-attainment area, or other smoke-sensitive area. In R18-2-1510, monitoring is related to the same size criteria. ADEQ solicits comment on whether these sizes, which have traditionally been used in the ADEQ Burn Guidelines, are useful distinctions or whether there is some other way of defining burns that are critical from an air quality standpoint.

5. **A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:**

Not applicable.

6. **The preliminary summary of the economic, small business, and consumer impact:**

Identification of the Proposed Rulemaking

Prescribed Forestry Burning, 18 A.A.C. 2, new Article 15, and repeal of R18-2-603.

A Brief Summary of the Information Included in the Economic, Small Business, and Consumer Impact Statement

(Please note that the entire Economic, Small Business, and Consumer Impact Statement is included here. No further materials are included in the rulemaking docket.)

These proposed rules manage prescribed burns such that the smoke from multiple burns, or the smoke from a single burn under adverse conditions, does not impact the health of persons living near the burn and does not impact visibility in any smoke-sensitive areas, such as federal Class 1 wilderness areas.

As discussed above in this Preamble, ADEQ has had prescribed forestry burning guidelines ("Interim Operations Guidance for Smoke Management in Arizona", ADEQ 1991) in place for several years. These Guidelines were created jointly between ADEQ

and the affected entities, each of whom has complied with the Guidelines since the time of their creation up to and including the present time. Most of the provisions in the proposed rule are codifications of the practices currently being followed under the Guidelines; therefore, the proposed rule creates few new economic impacts. The incremental costs or reduced costs that are created are described below.

The entities affected by the proposed rulemaking are as follows:

(a) United States Forest Service.

(b) United States Fish and Wildlife Service.

(c) National Park Service.

(d) Bureau of Land Management.

(e) Bureau of Reclamation.

(f) Department of Defense.

(g) Bureau of Indian Affairs.

(h) United States Soil Conservation Service.

(i) State Land Department.

(j) State Parks Department.

The U.S. Forest Service and the Bureau of Indian Affairs are, by far, the largest users of prescribed forestry burning. There are also, occasionally, private individuals who wish to conduct large-scale forestry or rangeland burning, who ask to be assisted by 1 of the federal or state land managers (F/SLMs) listed above. The private individual and the F/SLM then jointly follow smoke management procedures and share the costs.

Please note also that Indian tribes are invited to participate in state-wide smoke management practices but the state has no jurisdiction over tribal lands and the proposed rule cannot and does not mandate their participation. Therefore, any costs or benefits to Indian tribes in Arizona are not described in this document. The same is true for any private land manager, such as the Nature Conservancy, who has historically coordinated its prescribed burning with ADEQ although neither the current rules nor the ADEQ Burn Guidelines mandate their participation.

The following chart represents the total number of acres involved in prescribed forestry and rangeland burns in Arizona for the 1995 annual burn cycle, as well as the total emissions of particulate matter that were associated with those burns:

Total Acres Requested	Total Acres Approved	Total Acres Burned	Total PM10 Emissions (lbs)	Average Size Burned (acres)
325,257	295,665	104,261.5	28,994,473	52.76

The fuel types burned in 1995 were as follows: Timber 54%, grass 21%, piled slash 15%, and brush 10%.

The basic approach in determining total emissions is designed around determining the tons of fuel burned (known as an "activity level") and multiplying the activity level by an emission factor. This is done for each burn and the results summed to obtain estimates of PM10 emissions from prescribed burning. (Currently, the most readily available source of emission factors is provided in the U.S. EPA's publication Compilation of Air Pollutant Emission Factors, AP-42, Fourth Edition (AP-42), September 1985, Section 11.1. However, ADEQ and Arizona's F/SLMs are cooperating to research and verify more refined emission factors for the state of Arizona, partly using the database of information that will be created as a result of these rules. There is some evidence that Arizona emission factors will be lower than those in other states, due to the types and conditions of the fuels.)

Benefits

As can be seen from the above chart, prescribed forestry and rangeland burning in Arizona accounted for over 14,000 tons of particulate matter being added to the air during the 1995 burn cycle. This managed burning prevented uncontrolled wildfires that would have impacted air quality to a much greater extent. Prescribed burning creates physical barriers beyond which a wildfire cannot pass and it reduces the fuel available to a wildfire in a given area. Although entities such as the Grand Canyon Visibility Transport Commission have sought to establish the exact correlation between the number of acres burned and the number of wildfire acres (or amount of emissions) prevented, no such direct correlation is possible because of the large number of variables involved (weather, wind speed, terrain, fuel type, etc.).

Most particulate emissions from prescribed burning (over 90%) are less than 10 microns in diameter (PM10). This size particulate is considered to pose particular health concerns because PM10 is small enough to enter and remain in the human respiratory sys-

tem. Over 80% of the particulate matter is smaller than 2.5 microns, which is even more susceptible to being inhaled. This risk is recognized by the general public. People surveyed for the Arizona Comparative Environmental Risk Project ranked the air they breathed outdoors to be their 4th highest concern out of 20 environmental issues (ACERP, ADEQ 1995).

Adverse health effects result in a number of economic and social consequences, including:

1. Medical costs. These include personal out-of-pocket expenses of the affected individual (or family), plus costs paid by insurance or Medicare, for example.
2. Work loss. This includes lost personal income, plus lost productivity whether the individual is compensated for the time or not. For example, some individuals may perceive no income loss because they receive sick pay, but sick pay is a cost of business and reflects lost productivity.
3. Increased costs for chores and caregiving. These include special caregiving and services that are not reflected in medical costs. These costs may occur because some health effects reduce the affected individual's ability to undertake some or all normal chores, and he or she may require caregiving.
4. Other social and economic costs. These include restrictions on or reduced enjoyment of leisure activities, discomfort, or inconvenience (pain and suffering), anxiety about the future, and concern and inconvenience to family members and others.

The American Lung Association has estimated that a simple cold costs an average of $12 a day in lost productivity. Missing an entire day of work for respiratory reasons averages $60 per day. And the average cost of an emergency room visit for an asthma attack is estimated at $500. The following table, from the American Lung Association study, describes the monetary value of avoiding each of the health effects caused by particulate matter:

American Lung Association, "Dollars and Cents: The Economic and Health Benefits of Potential Particulate Matter Reductions in the United States" (June 1995)

Chapter 5. Monetary Valuation of Human Health Effects

Table 5-3

Summary of Selected Monetary Values for Morbidity Effects

Estimate per Incident (1st Q 95 Dollars)

Morbidity Effect	Low	Central	High	Primary Source	Type of Estimate
Adult chronic bronchitis	$150,000	$240,000	$390,000	Viscusi et al. (1991) Krupnick & Cropper (1992)	WTP
Respiratory hospital admission	$7,500	$15,000	$22,500	Krupnick & Cropper (1989)	Adjusted COI
Emergency room visit	$250	$500	$750	Rowe et al. (1986)	Adjusted COI
Child bronchitis	$160	$320	$480	Krupnick & Cropper (1989)	Adjusted COI

Restricted activity day	$30	$60	$90	Loehman et al. (1979)	WTP & Adjusted COI
Asthma symptom day	$13	$36	$60	Rowe & Chestnut (1986)	WTP
Acute respiratory symptom day	$6	$12	$17	Loehman et al. (1979); Tolley et al. (1986)	WTP
Selected Probability Weights for All Effects	33.3%	33.4%	33.3%		

WTP = Contingent valuation Willingness-to-pay estimate.

Adjusted COI = Cost-of-illness x 2 to approximate Willingness-to-pay.

The University of Arizona estimates that there are 242,627 asthmatics statewide in Arizona, or 1 out of every 16 people (Leibowitz 1993). (It is believed that the elevated rate is caused by asthmatics who move to Arizona hoping that the climate will improve their disease. Arizona's higher prevalence of asthma also may be attributed to offspring who have a higher predisposition to develop it. ACERP, ADEQ 1995.) In addition, numerous studies have found associations between PM10 pollution and mortality. Many of the studies correlate episodes of extremely high concentrations of particulates with increased mortality. Recent studies have also found correlations between increased PM10 pollution at lower levels and mortality from non-malignant respiratory diseases and cardiopulmonary diseases. While none of the epidemiological studies prove a causal effect, when taken together, the studies indicate a causal association exists, particularly among the elderly and those already suffering from a cardiopulmonary or respiratory disorder, such as asthma. (Studies referenced in ACERP Sec. 3, Chap. 13, ADEQ 1995.)

Mandatory prescribed forestry and rangeland burning rules assist in managing and lessening smoke impacts on the public at the time of the burn. This prevents hospital admissions for asthmatics, children, and the elderly. Managing the air quality impacts of prescribed burning also preserves the aesthetic qualities of the wilderness areas in which visibility is so highly prized. The exact benefits that are a result of this rulemaking are those that are over and above the benefits currently being enjoyed as a result of voluntary compliance with the ADEQ Burn Guidelines, and these are difficult to quantify further. The following discussion details the incremental costs and benefits to the affected F/SLMs and to ADEQ.

Costs

R18-2-1501. The Definition Section has no economic impacts, in and of itself.

R18-2-1502. The Applicability Section describes the affected entities but has no economic impacts by itself.

R18-2-1503. Annual Registration is currently in place at ADEQ, as a matter of policy, and has been used (as it will continue to be used under the proposed rule) as a tracking method only, so that ADEQ can have a general idea of what burns will occur in the coming 12 months. The registration of prescribed natural fires (PNFs) is the only new element, resulting in a marginal increase in cost for F/SLMs. No details on conducting the burn are required at this point; therefore, the additional new cost is quite small. Subsection (D) allows additional information to be requested by ADEQ in consultation with the F/SLM; it is unknown at this time what more might be needed or discussed, therefore, its impact cannot be quantified.

Subsection (F) allows electronic filing of registration forms in the future (since this is the stated intent of the F/SLMs at this time) and this change could result in lower filing costs.

No F/SLMs will have to hire new or additional staff to comply with this Section. ADEQ, in order to implement the entire proposed rule including this Section, can continue to rely on the U.S. Forest Service personnel currently provided to ADEQ under the Burn Guidelines. Currently, the F/SLMs provide for the staffing of 2 full-time positions, and ADEQ is providing their space and equipment. However, if that arrangement were to change, and ADEQ were to bear the entire cost, 2 full-time state employees (an Environmental Program Specialist and an Environmental Health Specialist II) would have to be hired at an estimated cost of $70,000.

R18-2-1504. The Burn Plan Section is less restrictive than the current ADEQ Burn Guidelines. The Guidelines, as well as current rule R18-2-603, require that each Burn Plan be known, detailed, and submitted in June of each year. The proposed rule does not require a Burn Plan until 14 days before the burn takes place. This reduces the burden on F/SLMs because not all burns contained

in a Registration actually take place, due to weather and fuel conditions. This allows for greater flexibility in planning.

Unless waived by ADEQ, modeling of potential smoke impacts, based on fuel type, topography, weather, and other factors is required in certain sensitive instances to determine where the health and visibility impacts might occur. Modeling costs, when required, can run from 20 cents per acre to $2 per acre, averaging $1 per acre in Arizona. Prescribed burns in Arizona tend to cover less than 300 acres; in 1995 the average size burned was 52.76 acres. Modeling costs would vary accordingly.

R18-2-1505. The elements of the Daily Burn Request are not new, with the exception of the reporting of wildfires greater than 100 acres. However, this economic impact is expected to be small since the proposed rule mimics the Wildfire Reporting System currently used by F/SLMs for their own purposes. The information required by the proposed rule is expected to track, for the most part, the information already reported by F/SLMs on Universal Form ICS 209. The only additional information required relates to "potential smoke and air quality impacts" for wildfires. It is not known at this time whether this information can be extrapolated from Universal Form ICS 209 or whether the form will have to be changed. ADEQ is soliciting comment on this point, as described earlier in this Preamble.

R18-2-1506. The elements of the Smoke Dispersion Evaluation are not currently contained in the ADEQ Burn Guidelines, but are a matter of current practice. However, the proposed rule would make these current practices mandatory. Therefore, as stated above, ADEQ, in order to implement the entire proposed rule including this Section, can continue to rely on the U.S. Forest Service personnel currently housed at ADEQ or, in the future, could hire 2 full-time state employees at an estimated cost of $70,000 to implement the program.

R18-2-1507. The Burn Accomplishments are currently produced pursuant to the ADEQ Burn Guidelines. The database of information is already kept by ADEQ. No economic impacts are associated with this Section.

R18-2-1508. The proposed Section on Prescribed Natural Fires (PNFs) is new. ADEQ is not currently approving or disapproving these burns. However, of all the affected entities listed at the beginning of this Economic Impact Statement, only the U.S. Forest Service and the U.S. Park Service are definitely using PNFs as a management tool at this time, and even these agencies are not yet using this tool frequently. This is because a PNF, in order to be controllable, must have burned-off perimeters or other physical barriers, such as waterways, to prevent its uncontrolled spread. Although areas are now being burned off to create these future boundaries, many areas are not yet ready for PNFs. In addition, for federal agencies, funding must be found for conducting PNFs, as they are funded separately from wildfires.

Most prescribed burns are less than 300 acres, whereas a PNF can be over 1,000 acres. Therefore, PNFs will eventually become an economical way to resolve heavy fuel problems and prevent wildfires (and their attendant air pollution problems). According to informal estimates by the U.S Forest Service, PNFs could increase to being 40% of the burns conducted by the 2 federal agencies using them. The Bureau of Land Management has also expressed interest in using PNFs. However, the actual use of PNFs cannot be predicted at this time.

The cost of complying with the Section on PNF Plans could be significant, because the F/SLM is asked to determine burn prescription and anticipated emissions, as well as potential smoke impacts. The information must be submitted to ADEQ within 72 hours. However, whether additional personnel would be needed to comply with this Section would vary from agency to agency, again, depending on their use of PNFs as a forestry health tool.

The Section on PNF Plans also contains some cost-savings provisions, in the form of consultation. Requiring consultation when an air quality problem has developed will result in the most practical solution to the problem that has appeared, and will prevent orders to suppress when they are not needed. An order to suppress a large fire can result in costs of $100,000 per day. Total costs to suppress have been known to reach more than $1,000,000 per day for extremely large fires, and the risk to human life for the firefighters must also be considered. To date, Arizona has not had this type of difficulty present itself, although neighboring states such as New Mexico have, and it is hoped that the consultation portion of the rule will prevent unnecessary suppression costs.

R18-2-1509. The proposed Section on Emission Reduction Techniques recites the current best management practices known to state and federal land managers and to the U.S. EPA. These practices are already in effect, to the extent possible, and are also currently recited in the ADEQ Burn Guidelines.

R18-2-1510. The Monitoring Section is also not new to the smoke management practices of Arizona. Even the establishment of remote automated weather stations (RAWS) is currently in use. However, it should be noted that consultation will govern the number of times that additional monitoring efforts will be required. Consequently, any new or additional impacts on the F/SLM, if any, are difficult to quantify at this time. Monitoring costs are estimated to average $1 per acre in Arizona. Prescribed burns in Arizona tend to cover less than 300 acres; in 1995 the average size burned was 52.76 acres. Monitoring costs would vary accordingly; however, it should be noted that monitoring costs also vary with the conditions of the burn and can become quite high in any situation where the burn threatens to become uncontrolled or where smoke may be reaching populated areas.

R18-2-1511. The requirements for Burner Qualifications are already a matter of current practice. Unlike other portions of this rulemaking, the Burner Qualifications are not contained in the ADEQ Burn Guidelines, but are employed by the F/SLMs for their own purposes. The rule therefore imposes no new costs.

R18-2-1512. The Public Awareness Program is not contained in current ADEQ rule or guideline. However, some F/SLMs currently engage in public education and outreach as part of achieving their own objectives. Since the Section makes the education program permissive, rather than mandatory, the cost to ADEQ may be zero or it may involve the time of 1 or more staff people (in conjunction with F/SLM staff people) in giving occasional presentations. No new employees will be hired by ADEQ to implement this Section, and it is unlikely that any F/SLM will hire additional employees due to this Section. If ADEQ chooses to implement

the education program, it may incur some minimal costs for renting meeting rooms in which to make presentations or to produced brochures jointly with the F/SLMs.

R18-2-1513. The Surveillance and Enforcement Section is both new language and is permissive in nature. Therefore, the economic impacts are difficult to assess. It is ADEQ's intent to become more active in the surveillance of prescribed forestry burns; however, no new full-time employees are planned to be hired.

Costs may accrue to an F/SLM who violates the rules, in the nature of civil penalties or the costs of containment or mop-up. However, the proposed rule does not change the effect of current law. A violation of current rule R18-2-603 would carry the same potential civil penalty and A.R.S. § 49-462 already allows ADEQ to seek legal restraint of any person who is "creating an imminent and substantial endangerment to the public health or the environment because of a release of a harmful air contaminant..."

R18-2-1514. The Oversight Section partly recites the report currently described in R18-2-603, but it expands on this report by seeking information associated with actual burns. There will be a significant cost to F/SLMs in preparing this report, depending on the level of detail that is achieved, and ADEQ seeks comment on this aspect of the rule. However, there will be several benefits associated with this same increase of effort -- the F/SLM will be able to use the information to conduct its prescribed burning program in a more cost-effective manner and ADEQ will be able to refine its rules by eliminating requirements that have not resulted in improved air quality. Both of these benefits (improved use of taxpayer dollars and improved air quality) carry over to the general public.

R18-2-1515. The economic impacts of the Section on Information Transfers are unknown at this time. Forms are currently provided both on paper and on computer disk. It is anticipated that electronic data transfer will eventually save money both for ADEQ and for the F/SLMs, but the relationship between the cost of computer hardware and software to the cost savings in time are difficult to assess. "Time" in this context does not refer to time saved in the preparation of documents (although this may be beneficial, also) but refers to more prompt approvals and disapprovals of burns by ADEQ, so that prime burning conditions can be taken advantage of by the F/SLM.

In conclusion, the incremental costs associated with this proposed rule are generally low and the air quality benefits are generally high. Also, in response to A.R.S. § 41-1055, the following statements apply: There are no economic impacts on political subdivisions. There are no economic impacts on private businesses, their revenues or expenditures. Possible employment of new persons has been discussed above, in context. There are no economic impacts on small businesses. There are no economic impacts for consumers; benefits to private persons as members of the general public are discussed above. There is no impact on state revenues, as no fees are charged in the smoke management program. There are no other, less costly alternatives for achieving the total goals of this rulemaking; however, in each Section where additional information or assistance may be obtained from the F/SLM, the mandate for that information was re-structured as a request following consultation with the affected agency, to avoid unreasonable or highly expensive demands by ADEQ.

7. **The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:**

Name:	Amy Wainright, Rule Development
Address:	Department of Environmental Quality 3033 North Central Avenue Phoenix, Arizona 85012-2809
Telephone:	(602) 207-2225
Fax:	(602) 207-2251

8. **The time, place, and nature of the proceedings for the adoption, amendment, or repeal of the rule or, if no proceeding is scheduled, where, when and how persons may request an oral proceeding on the proposed rule:**

Date:	June 11, 1996
Time:	12 p.m.
Location:	Flagstaff City Council Chambers 211 West Aspen Avenue Flagstaff, Arizona (Please call (520) 779-7690 for special accommodations pursuant to the Americans with Disabilities Act.)
Nature:	Public hearing on the proposed rules, with opportunity for formal comments on the record and an informal question-and-answer session.

Date: June 12, 1996

Time: 12 p.m.

Location: Department of Environmental Quality
Public Meeting Room
3033 North Central
Phoenix, Arizona

(Please call (602) 207-4795 for special accommodations pursuant to the Americans with Disabilities Act.)

Nature: Public hearing on the proposed rules, with opportunity for formal comments on the record and an informal question-and-answer session.

The close of written comment is June 17, 1996.

9. **Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:**
Not applicable.

10. **Incorporations by reference and their location in the rules:**
Not applicable.

11. **The full text of the rules follows:**

TITLE 18. ENVIRONMENTAL QUALITY

CHAPTER 2. DEPARTMENT OF ENVIRONMENTAL QUALITY AIR POLLUTION CONTROL

ARTICLE 6. EMISSIONS FROM EXISTING AND NEW NONPOINT SOURCES

Section
R18-2-603. ~~Forestry management~~ (Reserved)

ARTICLE 15. FOREST AND RANGE MANAGEMENT BURNS

Section
R18-2-1501. Definitions
R18-2-1502. Applicability
R18-2-1503. Annual Registration for Prescribed Burns
R18-2-1504. Burn Plan Contents
R18-2-1505. Burn Requests and Authorization
R18-2-1506. Smoke Dispersion Evaluation
R18-2-1507. Burn Accomplishment; ADEQ Recordkeeping
R18-2-1508. Prescribed Natural Fires (PNFs); Plan; Authorization; Monitoring; Inter-agency Consultation
R18-2-1509. Emission Reduction Techniques; Best Management Practices (BMP)
R18-2-1510. Monitoring
R18-2-1511. Burner Qualifications
R18-2-1512. Public Awareness Program
R18-2-1513. Surveillance and Enforcement
R18-2-1514. Oversight
R18-2-1515. Forms; Electronic Copies; Information Transfers

ARTICLE 6. EMISSIONS FROM EXISTING AND NEW NONPOINT SOURCES

R18-2-603. ~~Forestry Management~~ (Reserved)

~~A. All national parks and national forests having areas which extend into more than 1 county of the state of Arizona, as well all state parks and forests, shall be under the jurisdiction of the Director in all matters relating to prescribed burning or slash disposal.~~

~~B. Each entity mentioned in subsection (A) shall comply with the following:~~

~~1. Each national park, state park, national forest, or state forest hereinafter called forest will apply directly to the Bureau for an annual burning permit for all planned burning projects. Application will be made in the spring of the year, prior to June 1 for the ensuing fiscal year.~~

~~2. The application shall be in the form of a letter listing all projects. Enclosed with the letter will be copies of the Park Service or Forest Service approved burning plans for each planned project. A map of the burn and immediate surrounding area must accompany each plan.~~

~~3. The application and the Park Service or Forest Service plans will list the following:~~

~~a. Approximate date the project will start;~~
~~b. Location of project by sections, townships, or ranges;~~
~~c. Approximate elevation of project;~~
~~d. Aspect of any slopes;~~
~~e. Description of fuel to be burned;~~
~~f. Prescribed conditions for fire (e.g. time of day, fuel moisture, weather).~~

~~4. Each forest as part of the application will provide the Bureau with 1 emergency or 24 hour telephone number.~~

~~5. Each forest will notify the Bureau when a project planned starting date is later changed. Notification will be by telephone. Any other changes, such as fuel type, duration of burn, or location, should be included in this notification.~~

~~6. The determination to allow burning will be made on a day-by-day basis. It is the responsibility of each park or forest to telephone the Bureau for such a determination. Large fires and those that continue during nighttime hours will require special forecasts made by the national weather service, the Department's meteorologist, or by the permittee if forecast procedures are approved by the Department. On site meteorological measurements by the permittee may be required as inputs to dispersion forecasts and smoke management during the burn.~~

~~7. Once each year, on or before December 31, the Forest Service or Parks Service shall submit to the Bureau a report outlining the progress of research and development~~

~~concerning the effects of forest burn programs on air quality. Such report shall include, where applicable, innovations in the management of prescribed burning using meteorological data, as well as special burning methods, or innovative equipment. Alternatives to burning shall also be considered. Research as to cost effectiveness of the various methods should also be included.~~

ARTICLE 15. FOREST AND RANGE MANAGEMENT BURNS

R18-2-1501. Definitions

In addition to the definitions contained in A.R.S. § 49-501 and A.A.C. R18-2-101, the following definitions shall apply to this Article:

1. "ADEQ" means the Department of Environmental Quality.
2. "BMP" means best management practices as described in R18-2-1509.
3. "Burn prescription" means the pre-determined area, intensity of heat, and rate of spread required to attain planned resource management objectives.
4. "Burn project" means any active or planned prescribed burn, including a prescribed natural fire (PNF).
5. "Class I Area" means the mandatory areas designated pursuant to Section 169A of the Clean Air Act Amendments of 1990.
6. "Duff" means forest floor material made up of decomposing needles and other natural materials.
7. "Federal land manager (FLM)" means any departments, agencies, or agents of the federal government, including the following:
   a. United States Forest Service,
   b. United States Fish and Wildlife Service,
   c. National Park Service,
   d. Bureau of Land Management,
   e. Bureau of Reclamation,
   f. Department of Defense,
   g. Bureau of Indian Affairs,
   h. United States Soil Conservation Service.
8. "F/SLM" means a federal land manager or a state land manager.
9. "Local fire management officer" means a person designated by a federal or state land management agency who is responsible for fire management in a local district or area.
10. "Mop-up" means the act of extinguishing or removing burning material from a prescribed fire in order to reduce smoke impacts.
11. "National Wildfire Coordinating Group" means the national inter-agency group of federal and state land managers that shares similar wildfire suppression programs and that has established standardized inter-agency training courses and qualifications for fire management positions.
12. "Planned resource management objectives" include silviculture, wildlife habitat management, grazing enhancement, fire hazard reduction, wilderness management, cultural scene maintenance, weed abatement, watershed rehabilitation, vegetative manipulation, disease, and pest prevention or other public interest goals in support of land management agency objectives.
13. "Prescribed burning" means the controlled application of fire to wildland fuels which are in either a natural or modified state, under certain burn prescription conditions and smoke management prescription conditions that have been specified by the land manager in charge of or assisting the burn, to attain planned resource management objectives. Prescribed burning also includes a fire set or permitted by a public officer for the purpose of instruction in the methods of fighting fires. A prescribed fire may be ignited either by a trained fire specialist or by natural causes such as lightning.
14. "Prescribed Fire Manager" means a person designated by a federal or state land management agency who is responsible for prescribed fire activities for that agency.
15. "Prescribed natural fire (PNF)" means a wildland fire that is ignited by natural causes, such as lightning, and not by a trained fire specialist, but is subsequently allowed to continue burning using the same controls and for the same planned resource management objectives as prescribed burning.
16. "Smoke management prescription" means the meteorological conditions that affect smoke transport and dispersion in order to protect public health and welfare.
17. "Smoke management unit" means any 1 of 11 geographic areas defined by ADEQ whose area is based on primary watershed boundaries and whose outlines are determined by diurnal windflow patterns that allow smoke to follow predictable drainage patterns. A map of the state divided into 11 smoke management units is on file with ADEQ and is included in Appendix 1 of this Article.
18. "State land manager (SLM)" means any department, agency, or political subdivision of the state government that is responsible for wildland management.
19. "Wildfire" means a wildland fire that does not meet resource management objectives and that may threaten life, property, public health, or the ecosystem.
20. "Wildland" means an area in which development is essentially non-existent, except for pipelines, power lines, roads, railroads, or other transportation or conveyance facilities.

R18-2-1502. Applicability

A. Prescribed burning conducted or assisted by a federal or state land manager (F/SLM) shall be conducted according to the requirements of this Article.

B. The provisions of this Article shall apply to all areas of the state except Indian Trust lands. All federally managed lands and all state lands, parks, and forests shall be under the jurisdiction of ADEQ in matters relating to air pollution from prescribed burning.

C. Notwithstanding subsection (B), ADEQ and any Indian tribe may enter into a memorandum of agreement to implement this Article.

R18-2-1503. Annual Registration for Prescribed Burns

A. Each federal land manager and each state land manager (F/SLM) shall register with ADEQ all planned burn projects, including areas considered for potential prescribed natural fires (PNFs), for the following year.

B. The registration form shall be prescribed by ADEQ and shall include the following:
   1. The F/SLM's name, address, and business telephone number;
   2. The name, address, and business telephone number of an air quality representative who will provide technical support to ADEQ for decisions regarding prescribed burning. The same air quality representative may be selected by more than 1 F/SLM or Indian tribe;
   3. All burn projects and potential PNF areas planned for the upcoming year;

4. All burn projects that were completed during the previous year.

C. Each planned year shall ideally extend from August 1 of the registration year to July 31 of the following year. Each F/SLM shall use best efforts to register prior to August 1 of each year.

D. After consultation with the F/SLM, ADEQ may request additional information related to tracking burn projects, as needed.

E. A registration may be amended at any time. The failure to amend a registration shall not prevent a new prescribed burn from being approved, as long as the F/SLM has complied with the other provisions of this Article.

F. Although a facsimile shall be an acceptable means of complying with the deadline for registration, the original paper form shall be delivered to ADEQ for its records. ADEQ shall acknowledge in writing receipt of each registration. If ADEQ and the F/SLMs jointly develop an electronic filing and reporting system, the original paper form may be waived and ADEQ shall notify all F/SLMs of this change.

G. Each burn project registered with ADEQ, other than a PNF, shall have an accompanying burn plan on file with ADEQ, as described in R18-2-1504, no later than 14 days before the F/SLM requests permission to burn. A burn plan for a PNF shall be submitted as prescribed by R18-2-1508.

R18-2-1504. Burn Plan Contents

A. Each federal or state land manager (F/SLM) planning a prescribed burn, other than a prescribed natural fire (PNF), shall use the "Burn Plan" form supplied by ADEQ and shall file the completed form with ADEQ no later than 14 days before the F/SLM requests permission to burn. The form shall contain the following information used to facilitate the Daily Burn authorization process under R18-2-1505:

1. An emergency telephone number that is answered 24 hours a day.
2. Burn prescription.
3. Smoke management prescription.
4. The number of acres to be burned, the type of fuel, and the ignition technique to be used.
5. A map depicting the potential impact of the smoke. The potential impact shall be determined by mapping both the daytime and nighttime smoke path and down-drainage flow for 15 miles from the burn site, with smoke-sensitive areas delineated. The map shall use the appropriate scale to adequately show the impacts of the smoke.
6. Modeling of smoke impacts for burns greater than 250 acres in size, or greater than 50 acres in size if the burn is within 15 miles of a Class I Area, a PM non-attainment area, a carbon monoxide non-attainment area, or other smoke-sensitive area. Air quality modeling for these areas is mandatory unless waived either verbally or in writing by ADEQ. In consultation with the F/SLM, ADEQ shall provide guidelines on modeling.
7. The signature of the official submitting the Burn Plan on behalf of the F/SLM. Either a written signature or an electronic signature shall be acceptable.
8. After consultation with the F/SLM, any other information needed by ADEQ to assist in the Daily Burn authorization process.

B. A burn plan shall be submitted for a prescribed natural fire (PNF) as prescribed by R18-2-1508.

R18-2-1505. Burn Requests and Authorization

A. Each federal or state land manager (F/SLM) planning a prescribed burn, other than a prescribed natural fire (PNF), shall use the "Daily Burn Request" form supplied by ADEQ. The form shall contain the following information:

1. The F/SLM conducting the burn.
2. The area to be burned with reference to the burn plan, including size and legal location.
3. Any local conditions or circumstances known to the F/SLM that, if conveyed to ADEQ, could impact the Daily Burn authorization process.

B. After consultation with the F/SLM, ADEQ may request additional information to supplement the Daily Burn Request form and to aid in the daily burn authorization process. This information may include same day on-site and area meteorological, smoke dispersion, or air quality measurements.

C. The Daily Burn Request form shall be submitted to ADEQ as expeditiously as practicable, but no later than 2 p.m. of the business day preceding the burn. An original form, a facsimile, or an electronic information transfer are all acceptable submittals.

D. ADEQ shall approve, approve with conditions, or disapprove a burn on the same business day as the Burn Request submittal. ADEQ may communicate its decision by verbal, written, or electronic means, although a written or electronic reply shall be provided by ADEQ if requested by the F/SLM.

E. An F/SLM shall not ignite a prescribed burn without receiving the approval of ADEQ.

F. If weather conditions go out of smoke management prescription, from either the Burn Plan or an Approval with Conditions, the F/SLM shall cease ignitions and take appropriate action to reduce further smoke impacts.

G. Burn authorization for PNFs shall be as prescribed by R18-2-1508.

H. All wildfires greater than 100 acres in size shall be reported on a daily basis to ADEQ by the F/SLM in whose jurisdiction the wildfire occurs. The report shall include location, estimated control date, estimated control size, and potential smoke and air quality impacts.

R18-2-1506. Smoke Dispersion Evaluation

A. The determination by ADEQ to approve, approve with conditions, or disapprove a Daily Burn Request pursuant to R18-2-1505 shall be made using the factors described in subsection (B).

B. The determination shall be based on the following for each smoke management unit:

1. An analysis of the emissions from burns in progress and residual emissions from previous burns on a day-to-day basis.
2. An analysis of emissions from active PNFs and consideration of potential long-term emissions estimates.
3. An analysis of the emissions from wildfires greater than 100 acres in size and consideration of their potential long-term growth.
4. Local burn conditions.
5. Burn prescription and smoke management prescription from the applicable Burn Plan.
6. Existing and predicted local air quality.
7. Local and synoptic meteorological conditions.
8. Type and location of areas to be burned.
9. Protection of the national visibility goal for Class I Areas pursuant to Section 169(A)(a)(1) of the Act.
10. Minimization of smoke impacts in Class I Areas, roads or highways, airports, PM non-attainment areas, carbon monoxide non-attainment areas, or other smoke-sensitive areas.

R18-2-1507. Burn Accomplishment; ADEQ Recordkeeping

A. Each federal or state land manager (F/SLM) conducting a prescribed burn shall use the "Burn Accomplishment" form supplied by ADEQ. The form shall include the following:

1. Any known conditions or circumstances that could impact the daily burn decision process.
2. The subsequent acreage accomplishments.
3. The best management practices (BMP) for emission reduction described in R18-2-1509 that the F/SLM used in managing the burn.

B. For each burn approval, a Burn Accomplishment shall be submitted to ADEQ by 2 p.m. of the business day following the approved burning.

C. Burn Accomplishments may be submitted as an original form, a facsimile, or an electronic information transfer.

D. ADEQ shall maintain a record of Burn Requests, Burn Approvals/Conditional, Approvals/Denials, and Burn Accomplishments.

R18-2-1508. Prescribed Natural Fires (PNFs); Plan; Authorization; Monitoring; Inter-agency Consultation

A. A federal or state land manager (F/SLM) shall notify ADEQ of any potential prescribed natural fire (PNF) once it is projected to attain a size of 50 acres of timber fuel or 250 acres of brush or grass fuel.

B. For each PNF that has been declared as such by the F/SLM, the F/SLM shall complete a PNF Plan on a form supplied by ADEQ. The PNF Plan shall be submitted to ADEQ as soon as practicable but no later than 72 hours after the PNF is first observed. The PNF Plan shall contain the following information:
1. An emergency telephone number that is answered 24 hours a day.
2. Burn prescription and anticipated emissions.
3. The daily anticipated growth in the number of acres potentially burned.
4. The maximum allowable perimeter or size.
5. The type or types of fuel involved.
6. The anticipated duration of the PNF.
7. The anticipated weather on site.
8. A map depicting the potential impact of the smoke. The potential impact shall be determined by mapping both the daytime and nighttime smoke path and down-drainage flow for 15 miles from the burn site, with smoke-sensitive areas delineated. The map shall use the standard agency scale for that F/SLM.
9. Modeling or monitoring of smoke impacts, if requested by ADEQ after consultation with the F/SLM.

C. ADEQ will approve or disapprove the PNF Plan within 3 hours of receipt. Disapproval of the PNF Plan by ADEQ will require direct consultation with the requesting F/SLM. If ADEQ fails to respond to the submittal of the PNF Plan, approval of the PNF may be assumed by the F/SLM. The approval by ADEQ of the PNF Plan will be binding for the duration of the PNF project, unless the PNF creates a threat to public health or welfare. If a threat to public health or welfare is created, ADEQ shall consult with the F/SLM regarding the situation and the development of a joint action plan.

D. A Daily Status Report for each PNF shall be submitted to ADEQ for each day of the burn that the fire perimeter increases. The Report shall include daily anticipated growth and location.

R18-2-1509. Emission Reduction Techniques; Best Management Practices (BMP)

A. A person conducting a prescribed forestry burn shall implement as many best management practices (BMP) for emission reduction as are feasible for the specific burn and shall include the BMP in the Burn Accomplishment submitted pursuant to R18-2-1507.

B. The following measures are considered BMP:
1. Biomass reduction techniques such as yarding or consolidation of unmerchandisable material, multi-product timber sales, or public firewood access when economically feasible. When allowing public firewood access, provide information on the adverse impacts of using green or wet wood as fuel.
2. Burning in seasons that are characterized by meteorological conditions that allow for good smoke dispersion, especially March 15 through September 15.
3. Mass ignition techniques such as aerial ignition by helicopter to produce high intensity fires with short duration impacts.
4. Igniting burns under good-to-excellent ventilation conditions and suspending operations under poor smoke dispersion conditions.
5. Considering smoke impacts on local community activities and land users.
6. Burning only essential fuels to meet resource management objectives.
7. Minimizing duff consumption and smoldering through fuel moisture considerations.
8. When piles are constructed, minimizing dirt content by using hand piles or brush blades on material-moving equipment and by constructing piles under dry soil conditions.
9. Burning piles when other burns are not feasible, such as when snow or rain is present.
10. Using all opportunities that meet the burn prescription and all burn locations to spread smoke impacts over a broader time period and geographic area.
11. Burning during optimum mid-day dispersion hours, with all ignitions in a burn unit completed by 3 p.m. to prevent trapping of smoke in inversions or diurnal windflow patterns.
12. Using chunking of piles and other consolidations of burning material to enhance fuel consumption and to minimize smoke production.
13. Implementing maintenance burning in a periodic rotation mimicking natural fire cycles to reduce excessive fuel accumulations and subsequent excessive smoke production through smoldering or wildfire.
14. Utilization of prescribed natural fires and unplanned ignitions.
15. Managing smoke impacts as follows:
    a. Limiting smoke impacts to roads, highways, and airports to the amounts, frequencies, and durations consistent with any guidance provided by highway and airport personnel.
    b. Using appropriate signing if smoke will impact any roadways.
    c. Notifying control towers if smoke will intrude in any air traffic control zone.
    d. Determining nighttime impacts and taking appropriate precautions.
    e. Contacting appropriate authorities as needed regarding smoke or visibility impacts.

R18-2-1510. Monitoring

A. ADEQ may require a federal or state land manager (F/SLM) to monitor weather and air quality before or during a prescribed burn, excluding PNFs which are governed by R18-2-1508.

B. The following types of monitoring shall be required for burns greater than 250 acres in size, or greater than 50 acres in size if the burn is within 15 miles of a Class I Area, a PM non-attainment area, a carbon monoxide non-attainment area, or other smoke-sensitive area:

1. The release of pilot balloons (PIBALs) at the burn site to verify needed wind speed, direction, or stability.
2. Smoke plume measurements, using a format supplied by ADEQ.

C. Monitoring information required pursuant to subsection (B) shall be available to ADEQ on the day following the burn ignition.

D. After consultation with the F/SLM, ADEQ may also require the establishment of burn site or area-representative remote automated weather stations (RAWS) or their equivalent, having telemetry that allows retrieval on a real-time basis by ADEQ.

E. Monitoring information required pursuant to this Section shall be kept on file by the F/SLM for 1 year following the burn date.

R18-2-1511. Burner Qualifications

A. All burns shall be conducted by personnel trained in prescribed fire and smoke management techniques to the minimum level required by the federal or state land manager (F/SLM) conducting the burn.

B. A Prescribed Fire Manager or other local Fire Management Officer having jurisdiction over prescribed burns shall have smoke management training obtained through any of the following:
1. Successful completion of a National Wildfire Coordinating Group or agency-equivalent course dedicated to smoke management.
2. Attendance at an ADEQ-approved smoke management workshop.

R18-2-1512. Public Awareness Program

At the Director's discretion, a public education and awareness program may be initiated to inform the general public of the smoke management program described by this Article. The program shall address smoke impacts from prescribed fires and the role of prescribed fire in natural ecosystems. The program shall be initiated by ADEQ in cooperation with federal and state land managers.

R18-2-1513. Surveillance and Enforcement

A. ADEQ may use unannounced burn site inspections to verify the accuracy of the Daily Burn Request data described pursuant to R18-2-1505 as well as matching burn approval with actual conditions and smoke dispersion. On-ground site inspection procedures and aerial surveillance shall be coordinated by ADEQ and the F/SLM for safety purposes.

B. ADEQ may use remote automated weather station (RAWS) data to verify current and previous meteorological conditions at or near the burn site.

C. ADEQ may audit burn accomplishment data, smoke dispersion measurements, or weather measurements from previously conducted burns.

D. Deviation from procedures and authorizations approved by ADEQ shall constitute a violation of this Article. Violations may require containment or mop-up of any active burns and may also require, in the Director's discretion, a 5-day moratorium on ignitions by the responsible federal or state land manager (F/SLM). Violations of this Article are also subject to a civil penalty of not more than $10,000 per day per violation pursuant to A.R.S. § 49-463.

R18-2-1514. Oversight

A. An F/SLM making a change to any long-term established remote automated weather station (RAWS) shall 1st give ADEQ notice and an opportunity to comment on the change.

B. On or before August 15 of each year, each federal and state land manager (F/SLM) shall submit to ADEQ a report generally describing each of the following:
1. The emissions reductions for each project from the previous year as a result of using best management practices (BMP). Emissions reductions may be estimated using methods and emission factors developed jointly by ADEQ and F/SLMs.
2. The smoke management cost estimates for each active project from the previous year including estimates for monitoring, training, applying emission reduction techniques, research, and compliance with the requirements of this Article.
3. Any research on or development of innovative techniques for emission reductions.

R18-2-1515. Forms; Electronic Copies; Information Transfers

A. Any form required to be developed by ADEQ and completed by a federal or state land manager (F/SLM) shall be made available on paper and in electronically readable format.

B. After consultation with the F/SLM, ADEQ may require each F/SLM to provide data in a manner that allows for and facilitates electronic transfers of information.

NOTICE OF PROPOSED RULEMAKING

TITLE 18. ENVIRONMENTAL QUALITY

CHAPTER 13. DEPARTMENT OF ENVIRONMENTAL QUALITY SOLID WASTE MANAGEMENT

PREAMBLE

1. Sections Affected:	Rulemaking Action
Article 14	New Article
R18-13-1401	New Section
R18-13-1402	New Section
R18-13-1403	New Section
R18-13-1404	New Section
R18-13-1405	New Section
R18-13-1406	New Section
R18-13-1407	New Section
R18-13-1408	New Section
R18-13-1409	New Section

R18-13-1410	New Section
R18-13-1411	New Section
R18-13-1412	New Section
R18-13-1413	New Section
R18-13-1414	New Section
R18-13-1415	New Section
R18-13-1416	New Section
R18-13-1417	New Section
R18-13-1418	New Section
R18-13-1419	New Section
R18-13-1420	New Section
R18-13-1421	New Section

2. **The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**

Authorizing statutes: A.R.S. §§ 41-1003 and 49-104

Implementing statutes: A.R.S. §§ 49-761(A)(3), 49-761(B)(3), and 49-761(B)(4)

3. **The name and address of agency personnel with whom persons may communicate regarding the rule:**

Name: Katheryn A. Cross

Address: Department of Environmental Quality
3303 North Central Avenue, Eighth Floor
Phoenix, Arizona 85012-2809

Telephone: (602) 207-2222 or (800) 234-5677, ext. 2222 (Arizona only)

Fax: (602) 207-2251

4. **An explanation of the rule, including the agency's reasons for initiating the rule:**

Pursuant to A.R.S. § 49-761, this proposed rule sets forth handling, treatment, and disposal standards for biohazardous medical waste, which afford adequate protection for regulated medical waste handlers and for the public at large.

A. Background for these Proposed Rules

1. Biohazardous Medical Waste Defined

The solid waste "stream" is made up of waste from various sources including household-generated solid waste, hazardous waste, special waste, sludge, biohazardous medical waste, and non-biohazardous medical waste. All waste in the solid waste stream is subject to regulation pursuant to A.R.S. Title 49, Chapter 4. Where a source waste presents a specific risk to human health or the environment, regulations in addition to the general solid waste regulations are imposed.

Biohazardous medical waste can generally be described as medical waste from regulated generators which is either soaked with blood or which has come into contact with infectious agents capable of transmitting potentially deadly disease to humans. Non-biohazardous medical waste can be described as medical waste which is neither blood-soaked nor has it come into contact with an infectious agent. An example of non-biohazardous medical waste is a paper cup or a tissue in a physician's office used in the treatment of a common cold.

A.R.S. § 49-761(A)(3) requires that ADEQ adopt rules regarding the regulation of biohazardous medical waste. In contrast, A.R.S. § 49-761(B)(3) permits ADEQ to decide whether to impose additional regulatory requirements (beyond the solid waste requirements) upon non-biohazardous medical waste. In contrast to biohazardous medical waste, ADEQ believes that non-biohazardous medical waste does not pose a risk significantly different to that of general solid waste and is adequately regulated under the existing solid waste regulations. For this reason, the proposed rule sets forth handling and treatment standards only for biohazardous medical waste.

Infectious disease transmission is a chain of 4 events: the presence of an infectious agent; a sufficient number of infectious agents to cause an infection; a susceptible host, (a person who does not possess sufficient resistance to a particular infectious agent to prevent contracting a disease if exposed to it); and a portal of entry to the host, such as a break in the skin or an orifice. The purpose of the proposed rule is to set forth enforceable standards which, when met, break the chain of disease transmission.

2. The National Concern with Medical Wastes.

The national concern regarding the management of medical waste resulted from media reports about blood vials, needles, and syringes washing up on beaches in the northeastern states during the summers of 1987 and 1988. This led to beach closures and increased public concerns regarding public health and environmental risks.

As a result of this concern Congress passed the Medical Waste Tracking Act of 1988 (MWTA) codified at 42 U.S.C. 6692 et. seq. The MWTA established a voluntary 2-year demonstration tracking system for gathering information to evaluate the nature and risks posed by medical waste. This demonstration project has since ended, although several states involved have since incorporated all, or parts of the MWTA into their state medical waste regulations.

There were other national legislative and regulatory activities which occurred as a result of public concern over medical waste. For example, the U.S. Environmental Protection Agency (EPA), the Office of Technology Assessment, and the Center for Disease Control (CDC) all prepared medical waste management guidelines. In addition, the Occupational Safety and Health Administration (OSHA) proposed standards to reduce worker exposure to bloodborne pathogens in its Bloodborne Pathogen Rule.

The ADEQ recognizes that medical waste generators are currently governed by a variety of regulations which seek to protect differing classes of persons. The Joint Accreditation of Health Care Institutions, U.S. Department of Transportation, and OSHA all regulate the health care area, but the regulatory aims of each differ somewhat. Aims of these regulations include maintaining high quality patient care, safety during waste transport, and health care employee safety. These aims are distinct from the regulatory purpose of ADEQ's proposed rule, which is to address the proper treatment of the biohazardous medical waste stream once it leaves the facility.

To the greatest extent possible, ADEQ has attempted to recognize and not conflict with existing regulations. For example, ADEQ has worked with affected stakeholders to define biohazardous medical waste in such a way that it is consistent with OSHA'S Bloodborne Pathogen Rule and the Center for Disease Control regulations, among others.

3. Current regulation of medical waste in Arizona.

At the present time, only the Department of Health Services governs medical waste through its regulation of hospital environmental services. When the proposed rules become effective, then ADEQ will also govern medical waste. The state OSHA Bloodborne Pathogen Rule does not govern waste, although it regulates blood and blood products. There is some overlap of subject matter with the Bloodborne Pathogen Rule because ADEQ's proposed rule regulates blood and body fluids when they are discarded. A brief summary of Arizona medical waste regulation follows:

a.) Hospital medical waste in Arizona is regulated by the Department of Health Services (ADHS) rules R9-10-220 and R9-10-320 adopted in 1979, which set forth standards for hospital environmental services. These rules require that all potentially hazardous waste (defined as waste from isolation rooms and materials contaminated with blood or body secretions) be sterilized by incineration or autoclaving, and taken to a landfill. Rural hospitals with only 1 autoclave are permitted to double bag the waste and dispose it at an ADEQ approved landfill, if the landfill operator is notified and the waste is immediately buried.

b.) ADHS statutes require clinical laboratories to be licensed. Specimens and other potentially infectious materials must be sterilized prior to disposal in an approved landfill, incinerated, or with proper permission poured down a sanitary sewer.

c.) ADHS's statutory authority covers the licensing of health care institutions, and ADHS regulates what goes on inside the institution as a condition of receiving that licensing. Thus, in a general sense, ADEQ's proposed rule would regulate medical waste from the back door of an ADHS licensed facility to final disposal in a landfill. However, waste treated on-site at a facility currently regulated by ADHS and set out for disposal must meet the treatment requirements set forth in the proposed rule. ADEQ's rationale for this requirement lies in the fact that the Legislature has spoken most recently and directly to ADEQ and has mandated it to promulgate regulations for the proper handling and disposal of biohazardous medical waste. A facility or entity which generates biohazardous waste and sets it out for collection must follow the proposed rule requirements for packaging, storage, transportation, and treatment.

d.) There is no permit requirement under the proposed rule for facilities which treat waste on-site but the rule requires that treatment standards be met. The rule governs treatment facilities which accept for treatment biohazardous medical waste generated off-site. There is an exception for health care facilities which accept exempt waste, such as home-generated medical sharps or discarded drugs. These accepting facilities (absent other regulatory requirements) do not become subject to facility plan approval under A.R.S. § 49-762. ADEQ's rationale for this exemption is to encourage community hospitals to accept and treat home-generated biohazardous medical waste, thus reducing the volume of used medical sharps set out for residential solid waste collection.

e.) Within the broader solid waste stream, the Legislature singled out medical waste for special handling as noted above. ADEQ's authority to regulate biohazardous medical waste stems from this identification. ADEQ regulates solid waste disposal and air quality. It indirectly regulates medical waste through permitting via its air and water quality programs.

f.) ADEQ and 3 counties (Maricopa, Pima, and Pinal) enforce air quality standards by issuing permits to incinerators which dispose of medical, pathological, and animal waste.

g.) ADEQ has authority to abate environmental nuisances and illegal disposal of medical waste. ADHS has authority to abate public nuisances.

4. The Rule Was Developed With Considerable Public Participation.

ADEQ originally proposed the medical waste rules in June 1993. Some provisions of the rule proved to be controversial. Those provisions included a "small quantity generator" exemption, which continued to allow small amounts of untreated medical waste in the solid waste stream as long as the waste was properly packaged. Another controversial rule provision was the requirement that landfills accept untreated medical waste from small quantity generators. The small quantity generator exemption was proposed to provide regulatory flexibility to dentists, physicians, veterinarians, and others.

ADEQ considered this flexibility justified because of its concerns over access to treatment (particularly in rural Arizona) and disproportional cost to this class of generator. A 3rd controversial issue was whether the definition of biohazardous medical waste was overbroad and included solid waste which should not be regulated as biohazardous medical waste.

ADEQ responded by withdrawing the proposed rule and pledged to revisit these controversial issues with persons affected by the rule. To accomplish this, ADEQ held a series of facilitated medical waste roundtables with affected stakeholders and other interested persons to discuss the rule provisions and related regulatory concerns. ADEQ identified 6 classes of stakeholders and invited 5 representatives from each class. Those classes were: treatment interests; disposer interests (landfills); public interests (interested persons who are members of the public); regulatory interests (other state and county regulators); generator interests; and transport/hauler interests. Roundtable participants included the Arizona Hospital Association, Association of Professionals: Infection Control and Epidemiology, Browning Ferris Industries, Waste Management Incorporated, Arizona Medical Association, Arizona Association of Infectious Disease Physicians, among others.

Approximately 100 persons attended each of the 2 roundtable meetings. The roundtable audience consisted of invited panelists and open audience seating. In addition, a 3rd "treatment meeting" attended by approximately 50 persons was held to discuss technical capabilities of various treatment methods. At the 2nd roundtable held in January 1995 the stakeholders and the audience built upon the shared understanding reached at the 1st roundtable and discussed information from the treatment meeting.

As a result of all of these meetings, the stakeholders recommended that ADEQ delete the small quantity generator exemption and resolve the access and cost issues related to treatment by allowing treatment alternatives to autoclaving and incineration. In addition, stakeholders urged the ADEQ to simplify the definition of medical waste to make it more consistent with other nationally recognized regulatory definitions. Finally, stakeholders recommended that the ADEQ require refrigeration only if the waste is capable of decomposing.

Despite prolonged discussion, no group recommendation was reached regarding an appropriate treatment standard. Some participants stated that only sterilization was acceptable, while others took the position that decontamination was sufficient.

Participants advised ADEQ that agreement on the treatment issue was not possible given competition for market share and recommended that ADEQ determine the treatment standards.

6. Impact On Current Biohazardous Medical Waste Management

The proposed rule enlarges the universe of regulated medical waste from those hospitals currently regulated by ADHS rules. The proposed rule governs more people because it imposes requirements on generators, transporters, and treaters, in addition to those hospital generators traditionally regulated by ADHS. Also, it imposes requirements on generators to either treat waste on site or follow proper waste management because the ADEQ's proposed rules regulate the waste stream after it leaves the facility. Thus, these rules impose additional requirements related to transportation, manifesting, and disposing of biohazardous medical waste.

On-site incinerators and on-site steam sterilization units (autoclaves) in use on the effective date of the rule are not required to meet equipment specifications and requirements of R18-13-1421, but are required to meet the treatment standards of R18-13-1412. However, on-site alternative technology in use on the effective date of the rule must meet the equipment specifications and requirements of R18-13-1421 but is allowed 180 days to do so.

ADEQ's rationale is based on the fact that incinerators and steam sterilization technology automatically achieve a higher standard (sterilization) than required, in contrast to alternative technologies. Because existing incinerators and autoclaves already meet this higher standard, ADEQ believes that protection of human health is achieved as long as these units meet the required treatment standards. Therefore, documentation of equipment specifications and a certification that the equipment is capable of meeting the treatment standards is not required for existing equipment. It is required for incinerators and autoclaves which come into use after the effective date of the rule. ADEQ believes that the economic burden of requiring this paperwork from existing incinerators and autoclaves does not outweigh the benefits. In contrast, for a new incinerator and autoclave unit, the cost of providing this information is relatively minimal. In addition, existing incinerator and autoclave units have a record of effectiveness spanning many years whereas alternative technologies, while effective, are relatively new.

A medical waste treatment facility in operation on the effective date of this Article is subject to plan approval requirements, and has 180 days to come into equipment specification requirements.

7. Home-generated Biohazardous Medical Waste

ADEQ would like to initiate public discussion regarding medical waste generated in the home but which is administered by home health agencies and related home health care providers in the course of changing bandages and giving injections. At this time, ADEQ considers the homeowner the generator of biohazardous medical waste and considers any provider of health care the agent of the homeowner. Under this approach, all biohazardous medical waste generated in a home is exempt from this Article regardless of who administers the care.

The ADEQ is aware of an increasing national trend to shift administration of health care to the home which is resulting in an increased volume of home-generated biohazardous medical waste. This shift to home health care occurs when

medical procedures are administered on an outpatient basis rather than an inpatient basis, when earlier hospital discharge takes place, or in other similar situations. As this stream of exempt waste is growing larger, the corresponding hazards it poses increases. However, ADEQ is aware of enforcement problems regarding home-generated medical sharps, and is attempting to identify alternatives to regulation which would protect human health. At this time, ADEQ expects that this issue will be addressed after the proposed rule is effective.

8. Impact of the Federal DOT Regulations on the Proposed Rulemaking.

ADEQ is aware of impending U.S. Department of Transportation regulations which may preempt state law regarding transportation of biohazardous medical waste. When these federal regulations are effective, ADEQ plans to amend the state rule so that it refers to, and is consistent with, the federal rule.

B. Specific Section-by-Section Explanation of this Proposal: The Section-by-Section explanation of these proposed rules is organized as follows:

R18-13-1401. Definitions

As noted above, the proposed definition of biohazardous medical waste is consistent with major regulatory definitions. This provides a common frame of reference for persons who generate or come into contact with biohazardous medical waste.

The 6 classes of biohazardous medical waste are: cultures and stocks of infectious agents and associated biologicals; waste human blood and blood products referring to discarded waste human blood and blood components, such as serum and plasma; pathological wastes removed during autopsy or other medical procedures; medical sharps including hypodermic needles, syringes, pasteur pipettes, glass contaminated with blood or speciums, and scalpel blades; research animal waste including contaminated animal carcasses, body parts, and bedding of animals that were exposed to infectious agents; and isolation waste generated by humans isolated to protect others from highly virulent diseases.

R18-13-1402. Applicability

The medical waste stream begins at the point of generation and continues through handling until treatment. The proposed rule applies to any person who generates, stores, collects, transports, treats, or disposes of biohazardous medical waste. This rule recognizes that the Department of Health Services, not the ADEQ, regulates activities inside a health care facility. For this reason, the proposed rule begins regulation of biohazardous medical waste at the point at which it is set out for collection and disposal. Biohazardous medical waste set out for disposal must meet the standards set forth in this rule.

The proposed rule fixes responsibility on the generator for retrieval and proper disposal of biohazardous medical waste which is found to be improperly disposed. Biohazardous medical waste which also contains radioactive materials is to be managed as radioactive waste until the time that the radioactive component has sufficiently decayed. Biohazardous medical waste treated as set forth in the proposed rule, becomes solid waste and is handled in accordance with solid waste requirements. Under the proposed rule, health care facilities which accept exempt waste, such as home-generated medical sharps or discarded drugs, do not (absent other regulatory requirements) become subject to facility plan approval under A.R.S. § 49-762.

R18-13-1403. Exemptions

The proposed rule does not govern medical waste generated in a home environment (whether by self-care or administered by others.) However, ADEQ always urges home generators to properly package medical sharps by securely sealing them before putting in municipal solid waste collection.

Another exemption is proposed for biohazardous medical waste which is poured down a sanitary sewer under authority of the local waste water treatment facility in compliance with federal and local permit conditions. An exemption is granted for unused medical sharps returned to the manufacturer via the U.S. Postal Service.

The proposed rule grants a partial exemption to a multi-use vehicle operated by health personnel when conducting routine business as long as the waste is properly packaged, separately contained within the vehicle, the container is decontaminated periodically, and biohazardous medical waste is transported to a treatment facility. Also, a partial exemption is granted to a person who transports biohazardous medical waste between multiple properties owned or operated by the same owner or governmental entity if the waste is properly packaged.

The proposed rule does not govern human corpses or remains intended for interment or cremation; nuclear material covered by the Atomic Energy Act of 1954; or hazardous waste covered by ADEQ's hazardous waste requirements.

R18-13-1404. Transition

An on-site incinerator or on-site sterilization unit which is brought into operation on or after the effective date of this Article is subject to equipment specification requirements. An on-site alternative medical waste treatment unit in operation on the effective date of this Article must come into compliance with the equipment specification requirements within 180 days after the effective date of this Article.

A medical waste treatment facility in operation on the effective date of this Article is subject to plan approval requirements. Within 180 days after the effective date of this Article, the facility shall come into compliance with the equipment specification requirements.

R18-13-1405. Generators

Under the proposed rule, a generator of biohazardous medical waste may either treat waste on-site or transport waste to a medical waste treatment facility. The proposed rule sets forth the respective provisions which govern, depending upon whether the waste is treated on or off-site.

R18-13-1406. Segregation

A generator of medical waste may segregate biohazardous medical waste from non-biohazardous medical waste and handle only the biohazardous medical waste in accordance with the proposed rule. Under the proposed rule, co-mingled biohazardous and non-biohazardous waste is regulated as biohazardous medical waste.

R18-13-1407. Packaging

The proposed rule requires that biohazardous medical waste must be packaged in either a red biohazard bag or a reusable container. A biohazard bag must meet specified standards and must be tied to prevent leakage of contents or breakage during storage, handling, or transport. A reusable container must be leakproof and easily cleanable. If disposable packaging is used, the packaging is handled as biohazardous medical waste. Further, encapsulation is acceptable if the encapsulation agent meets the treatment standards in R18-13-1412.

R18-13-1408. Storage

Because a primary purpose of the proposed rule is to prevent disease transmission by breaking the chain of disease transmission, rule provisions focus on limiting contact to the waste. Storage areas for biohazardous medical waste are to have restricted access and be separate from the general traffic flow. Under the proposed rule, waste capable of decomposing ("putrescent waste") may be kept unrefrigerated for 7 days if it is properly contained and does not create a nuisance. Objectionable odors and off site migration of odors must be minimized. The universal biohazard hazard symbol must be displayed on each container and a visible written warning must be printed in both English and in Spanish.

Under the proposed rule, a container of biohazardous medical waste may be stored alongside a container filled with general solid waste if there is no co-mingling of the waste. If co-mingling occurs, the entire quantity of waste is considered biohazardous medical waste and is handled in accordance with the rule provisions.

The proposed rule requires that if biohazardous medical waste is stored on-site longer than 90 days from the date the waste is placed in the collection container, the facility must have facility approval.

R18-13-1409. Transportation

Under the proposed rule, a transporter accepts only biohazardous medical waste which is properly packaged and accompanied by a manifest. The rule requires that biohazardous medical waste is transported in a timely manner: delivered within 24 hours of pick up unless refrigerated; it is not held longer than 4 days unless held at an ADEQ-approved facility; and there is no direct transfer of waste from 1 vehicle to another.

Under the proposed rule, vehicles which are used to transport biohazardous medical waste must possess any required permits, licenses, or local governmental approval. Vehicles must be equipped so that accidental contact with the biohazardous medical waste is minimized, and the cargo compartment must be decontaminated periodically as well as when there are signs of visible contamination. Under the proposed rule, biohazardous medical waste is accompanied by a manifest and a transporter requests that the destination facility provides written confirmation that the waste was received. The rule requires follow-up action if the confirmation is not provided.

R18-13-1410. Transporter Spills; Accidents

The proposed rule requires that spills of biohazardous medical waste are managed in accordance with local, state, and federal rules regarding such an occurrence. In addition, spills must be reported within 2 days to ADEQ, the generator, and the local health department.

The proposed rule holds transporters are responsible for cleaning up spills which occur while the waste is in the transporters possession. The proposed rule requires transporters to carry spill containment and clean-up kits including absorbent material, personal protective gear, and first-aid kit.

R18-13-1411. Manifest

The proposed rule requires that a manifest accompany the biohazardous medical waste from the point of generation to the treatment facility, including all intermediate handling facilities. The manifest remains with the person who takes physical possession of the waste. The manifest must be kept for 6 months. A completed manifest contains information including name and address of the generator, transporter, receiving facility, and any transfer station; the quantity of waste delivered and date generated and delivered. A transporter who accepts biohazardous medical waste provides the generator with a signed copy of the manifest to signify acceptance.

R18-13-1412. Treatment Standards

A. Treatment standards. In Arizona, incineration and autoclaving (steam sterilizing) have been the traditional methods of treating medical waste. For this reason, all other treatment methods are considered alternative treatment technologies. In exploring the various treatment technologies and to determine an appropriate treatment standard, the ADEQ consulted

the "Technical Assistance Manual: State Regulatory Oversight of Medical Waste Treatment Technologies" (Treatment Manual), prepared by the State and Territorial Association on Alternate Treatment Technologies (April 1994). The Treatment Manual has been used by several other states in determining regulatory treatment standards and ADEQ discussed its use of the Treatment Manual with stakeholders at the roundtables.

As noted earlier, stakeholders advised ADEQ that they were unable to come forth with recommended treatment standards because of the varying capabilities of competing technologies and market share interests. For example, incineration and autoclaving achieve sterilization while several other technologies, such as microwaving, do not.

The Treatment Manual describes a range of treatment levels from sterilization (Level IV); high disinfection (Level III); intermediate disinfection (Level II) to low disinfection (Level I).

The proposed rule sets forth Level III as the standard. In choosing this standard, the ADEQ considered the arguments set forth in the Treatment Manual and its recommendation that Level III be required of all emerging medical waste technologies. ADEQ intended to create a regulatory scheme flexible enough to allow generators to make economic decisions appropriate to their needs. One way of creating this flexibility is to allow emerging medical waste treatment technologies which meet the treatment standards entry into the Arizona market. This allows market forces to resolve the access to treatment and disproportionate cost issues faced by rural generators and small generators.

Under the proposed rule, biohazardous medical waste treated to achieve a Level III classification is regulated as solid waste. A Level III classification is defined as inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria at a 6 Log_{10} reduction or greater; and inactivation of *B. stearothermophilus* spores or *B. subtilis* spores at 4 Log_{10} reduction or greater.

B. Indicators of treatment efficacy. The proposed rule sets forth representative biological indicators which demonstrate that treatment efficacy has been achieved. In addition, it sets forth the method by which microbial inactivation is quantified and also provides an alternative quantitative measurement of microbial inactivation. Acceptable demonstration of compliance includes demonstration submitted from a laboratory licensed by the Department of Health Services.

C. Manufacturer's specifications are followed. Under the proposed rule, ADEQ does not approve medical waste treatment technologies. Where a manufacturer states that a given technology is suitable for a given classification of waste, ADEQ will accept treatment which follows the manufacturer's specifications as long as Level III treatment is achieved. Thus, it will accept a manufacturer's determination that the type of waste (1 of the 6 classes described above) is appropriate for a given treatment technology.

D. Encapsulation, grinding, and compaction are not considered treatment. The proposed rule requires that encapsulated biohazardous medical waste is treated before encapsulation, or the encapsulating material itself achieve Level III treatment. In addition, medical sharps must be rendered "incapable of being reused". ADEQ considers "incapable of being reused" as incapable of being used for their original purpose.

R18-13-1413. Medical Waste Treatment Facility; Plan Approval Requirement

Under the proposed rule, facility plan approval is required for a medical waste treatment facility where mandated pursuant to A.R.S. § 49-762. Plan approval is granted where the applicant successfully demonstrates compliance with this Chapter. In addition, the treater shall have solid waste plan approval from the Department. If incineration technology is used, an air quality permit is required pursuant to A.R.S. Title 49. An air quality permit may in the future be required if alternative treatment technology is used which emits air pollutants.

R18-13-1414. Treatment Certification Statement

The proposed rule requires that the treater sends a treatment certification statement to the generator, and keep 1 copy on file to be made available to the landfill operator upon request. The purpose of the treatment certification statement is to make available written documentation that the biohazardous waste has in fact been treated. The treatment certification statement includes the name, address, telephone number, and signature of the person or facility responsible for treatment, and the date of treatment.

R18-13-1415. Disposal

Under the proposed rule, biohazardous medical waste which has been treated by a method which achieves the treatment standards described in the proposed rule may be sent to an ADEQ-approved landfill or to a recycling facility.

R18-13-1416. Medical Sharps

The proposed rule requires that medical sharps be treated and rendered incapable of being reused or are packaged and sent to a treatment facility via a postal mail-back system.

R18-13-1417. Mixed Biohazardous Waste and Hazardous Waste

Under the proposed rule, biohazardous medical waste which is mixed with radioactive materials is handled in accordance with the more stringent standard. Therefore, mixed waste containing radioactive materials is governed by 12 A.A.C. 1.

A mixture of biohazardous medical waste, hazardous waste, and radioactive waste is governed by both hazardous waste and radioactive waste statutes and regulations. An exception to the manifest requirement is given to biohazardous medical waste when mixed with radioactive materials and returned to a supplier, if the radioactive materials are properly packaged and shipped directly

to the supplier for decay in storage. In this exception, the supplier is considered the generator and is responsible for treatment. The proposed rule does not release the supplier from any manifests required by other federal, state, or local regulations.

R18-13-1418. Discarded Drugs

The proposed rule requires that discarded drugs not returned to the manufacturer be destroyed by any method which prevents their reuse. Discarded drugs may be flushed down a sanitary sewer with permission from the local waste water treatment facility. Under its solid waste authority, ADEQ intends to prevent the unauthorized use of discarded drugs.

R18-13-1419. Body Parts

Under the proposed rule, if a treatment method other than incineration is used, recognizable human tissue, organs, body parts, and infected animals must be further processed to render such waste nonrecognizable. Aesthetic concerns underlie this requirement.

R18-13-1420. Medical Waste Treatment Facility; Design and Operational Requirements

The proposed rule requires that after receiving plan approval, a transfer facility operator which accepts biohazardous medical waste shall do so only if the waste is properly packaged and accompanied by the manifest. A transfer facility operator must keep the biohazardous medical waste separate from other solid waste, refrigerate it if kept longer than 24 hours. Biohazardous medical waste must be delivered to a Department approved facility.

After receiving plan approval, a treater must follow proper storage and treatment standards, and maintain written documentation regarding proper operation and equipment maintenance. Waste is treated within 24 hours of receipt of the waste or refrigerated. Storage of refrigerated biohazardous medical waste is not to exceed 90 days.

R18-13-1421. Equipment Specifications; Requirements

Under the proposed rule, the treater maintains written documentation regarding the proper operation and maintenance of the treatment equipment. In addition, the treater maintains a certification that the equipment, when operated properly, is capable of achieving the treatment standards.

5. **A showing of good cause why the rule is necessary to promote a state interest if the rule will diminish a previous grant of authority of a political subdivision of this state:**

Not applicable.

6. **The preliminary summary of the economic, small business and consumer impacts:**

A. OVERVIEW

1. Introduction

The proposed rulemaking, upon which the preliminary economic, small business and consumer impact statement (EIS) was developed, is identified as 18 A.A.C. 13, Medical Waste (new).

This Section summarizes the incremental impacts expected as a result of promulgating this rule. The expression "incremental impacts" means probable costs and benefits that would occur as a result of this rule becoming effective, compared to the costs and benefits in absence of this proposed rule. For example, past expenditures, and any future ones that would be incurred regardless of this rule, would not be considered incremental costs.

Research findings of this EIS are a result of numerous data-gathering activities that are described later in this EIS summary. As a result of these activities, the ADEQ reached 3 conclusions:

1.) Overall impacts on all regulated parties should be minimal.

2.) Compliance costs mainly should consist of treatment costs for generators currently not treating their biohazardous medical waste.

3.) Environmental and pubic health benefits should accrue from improved management of Arizona's biohazardous medical waste.

2. Need for Rule

ADEQ believes that over the last several years the proportion of generators that treat their biohazardous medical waste has been increasing. If a generator survey had been undertaken in 1992, it likely would have shown a treatment rate significantly less than what was discovered in 1995. This rulemaking has relatively low compliance costs because medical-service providers significantly have increased the extent to which they treat biohazardous medical waste even in the absence of a regulatory program. Numerous factors have contributed to a high-treatment rate among Arizona's generators (see A.4 below). Even though there is a significant trend toward treatment, there still is a proportion of generators that currently are not treating their biohazardous medical waste. On almost a daily basis, the ADEQ receives telephone calls about improperly disposed of medical waste. Therefore, this rule is necessary to eliminate "problematic exposures" of medical waste. Without this rule, ADEQ would not have the ability to enforce rule provisions. Most importantly, there would be no guarantee that generators who presently treat their biohazardous medical waste would continue to treat.

There is a need for this rule from an environmental and public health perspective. The improper management of medical waste creates a potential for the spread of communicable diseases, such as human immunodeficiency virus (HIV) and hepatitis B. Furthermore, the need for this rule is intrinsically linked to anticipated benefits (see A.5. below). Although

the majority of compliance costs already have been incurred through voluntary compliance by the medical-service providers, corresponding benefits have been realized in anticipation of this rule. However, there still are costs to be incurred and benefits yet to be realized as a result of implementing this rule. Thus, the focus of this EIS is on the small proportion of generators currently not treating their biohazardous medical waste.

3. Entities Impacted

This rule is expected to impact the following entities: generators, treaters, transporters, medical waste handlers (e.g., refuse haulers and landfill personnel), and the public at large. The public at large includes private citizens, consumers of health-care services, and some medical waste handlers that may come into contact with medical waste during their daily work. The universe of generators includes 2 groups: hospital generators and nonhospital generators. Nonhospital generators comprise 7 categories: physicians' offices and clinics, dentists' offices, nursing and long-term care facilities, veterinarians, funeral homes/crematories, laboratories, and home health agencies. These groups also include a small proportion of public generators (e.g., county jails, health departments, clinics, and hospitals). Based on survey findings, these public generators are expected to be impacted in the same manner as the private generators. Table 1 summarizes the findings of the generator survey.

Treaters include commercial facilities, for example, that incinerate, autoclave, or microwave biohazardous medical waste. Treaters also include companies which sell mail-back kits that dentists' offices, home care agencies, and other small quantity generators can use to dispose of biohazardous medical waste. Their waste predominately is comprised of medical sharps, which can be mailed-back in containers for subsequent treatment and disposal.

4. Factors Contributing to Minimal Impacts

The overall impacts of this rule are minimal because of several factors. These factors have acted as a catalyst for generators to treat their biohazardous medical waste even in the absence of a state environmental regulatory program. The ADEQ discovered that biohazardous medical waste is being treated at an overall rate greater than otherwise might be expected. Factors that have contributed to a high-treatment rate are summarized below:

a. National attention has been focused on the management of medical waste, beginning a decade ago when medical waste appeared on beaches and in other public places.

b. The Medical Waste Tracking Act of 1988, a 23-year demonstration program to track medical waste in certain eastern states (1989-1991), was implemented by the EPA. Additionally, the Agency for Toxic Substances and Disease Registry, U.S. Public Health Service, has been mandated by Congress to prepare a report on the health effects of medical waste.

c. The regulated industry and public have anticipated since 1992 that the ADEQ would promulgate biohazardous medical waste rules.

d. The Department of Health Services has promulgated rules which require Arizona's hospitals to treat potentially hazardous medical waste (1979).

e. Municipal solid waste landfills in Arizona have refused to accept untreated biohazardous medical waste.

f. The federal Occupational Safety and Health administration (OSHA) has promulgated occupational exposure standards to protect worker health and safety.

g. The EPA Office of Technology Assessment has published a guide for the management of infectious medical wastes (1986).

h. The Center for Disease Control has published several medical waste management documents on hospital waste (1983, 1985, 1987, and 1988).

i. National professional associations, commissions, and societies have advanced various guidelines for the healthcare industry (e.g., American Hospital Association and Joint Commission on Accreditation of Healthcare Organizations).

j. Many generators have considered the potential liability for untreated or improperly disposed of biohazardous medical waste.

k. Arizona treaters aggressively have marketed their services to all categories of generators and convinced many that they need to have their biohazardous medical waste treated.

5. Rule Benefits

Benefits are expected to accrue to medical-service providers and to the public at large. Because of the public's concern about the proper disposal of medical waste and the fear (both real and imagined) of communicable diseases and infectious agents, improved management of medical waste should have wide-spread impacts. For example, reducing the potential exposure to untreated, and otherwise improperly managed biohazardous medical waste, is expected to lessen the probability of occurrence of injury, infection, or disease. Likewise, improved management of biohazardous medical waste is expected to reduce the potential for environmental degradation. From an occupational standpoint, it could mean

less contact with potentially hazardous biohazardous medical waste for some medical waste handlers (e.g., waste haulers and landfill personnel).

Other possible benefits from the improved management of medical waste could include the following: (1) Reduced incidents of improper disposal of biohazardous medical waste by generators; (2) Improved handling and less careless behavior by some health-care workers, waste haulers, and landfill personnel; (3) Reduced waste from generators by improved source separation of non-biohazardous medical waste (not overclassifying biohazardous medical waste); (4) Less regulatory uncertainty and improved awareness by all affected parties; and (5) Improved professional image. This last potential benefit could be more important than one might expect because the public generally has an aversion to discarded medical sharps, body parts, body fluids, and used bandages.

The regulatory cost of this rule is the cost to properly manage biohazardous medical waste to reduce the potential spread of infection. The ADEQ expects this cost to be borne equitably by all entities responsible for generating biohazardous medical waste because both large and small generators are required to treat. Under this rule, generators have flexibility in making treatment decisions that are economically sensible because the ADEQ does not mandate a specific treatment methodology, but instead sets forth specified treatment standards that must be met. This approach allows alternative treatment methodologies which meet the specified standard to enter the Arizona market, thus creating more numerous treatment options for generators. In this way, a generator has greater flexibility to make economically sound decisions appropriate to his or her situation.

In addition, this rule will ensure that generators who currently treat their waste on a voluntary basis continue to do so, and comply with other rule provisions. Generators who are not presently treating their biohazardous medical waste will be expected to begin treating and to comply with all rule provisions. Without this rule, there is no requirement to properly manage biohazardous medical waste. As a result of anticipated benefits, the ADEQ expects probable benefits to outweigh probable costs.

B. RESEARCH FINDINGS

1. Data-gathering Activities

The primary data source is a generator survey conducted mid-year 1995. A stratified, random sample methodology was used to reduce sampling bias and to improve the reliability and validity of the survey. The ADEQ mailed surveys to more than 1,000 generators out of an estimated universe of nearly 7,300 generators. The overall sample size was relatively small at 3.7%. Other data sources include conversations with treaters, pharmacies, state associations (e.g., Arizona Hospital and Healthcare Association and Arizona Dental Association), companies which sell mail-back kits for sharps disposal, and a company which sells a system to encapsulate sharps.

In September 1995, the ADEQ sent surveys to 4 treaters and 2 transporters which have established businesses in the state. The ADEQ learned from telephone conversations that all transporters, except for 1, are owned and operated by treatment companies. One additional treater located in New Mexico that transports waste out of Arizona was mailed a survey. None of the treaters or transporters responded to the survey.

Arizona's treaters currently are following acceptable industry standards for such areas as: manifesting, recordkeeping, transporting, and treating. In fact, 3 out of 4 treaters already have received plan approval for operation of their facilities. These treaters continue to cooperate with the ADEQ in anticipation of this rule.

2. Generator Treatment Rate

The ADEQ concluded from the generator survey that about 95% of Arizona's generators currently are treating their biohazardous medical waste. This treatment rate includes generators transferring their biohazardous medical waste to another division or generator, presumably for treatment. This high-treatment rate may be overstated because of sampling errors, nonresponse bias, and other factors.

Treatment may be performed either on-site or off-site. Generators which perform on-site treatment must meet the rule standards for treatment efficacy or transfer to an off-site facility which meets these standards. Some generators may use their own treatment devices on-site, such as an autoclave. Other generators may use off-site treatment, i.e., biohazardous medical waste is transferred to a commercial treatment facility (treater). A proportion of small quantity generators that predominantly produce medical sharps may purchase mail-back kits, which represent another option of off-site treatment previously mentioned.

3. Cost to Generators Not Treating

If 95% of the generators are currently treating, the remaining 5% which have chosen not to treat their biohazardous medical waste, will bear the incremental costs of treating. The annual compliance cost for these generators is estimated at $350,000. However, because of the small sample size and other factors, the compliance cost for generators not treating may be more than the amount inferred from the generator survey data.

The cost to individual generators not treating will vary according to the amount of biohazardous medical waste they produce and to the category of generator they belong. Average treatment costs are a result of 4 factors: (1) Quantity of biohazardous medical waste produced, (2) Pickup schedule, (3) Number of containers to be picked up, and (4) Distance from the treater (in some cases). For example, dentists' offices, which only produce a monthly average of 4 pounds, are expected to pay an average amount of $420 annually. In contrast, physicians' offices and clinics are expected to pay

$1,920 annually, or almost 5 times that amount. For further cost details and other survey findings, refer to Table 1.

It is evident from Table 1 that dentists' offices generate the least amount of biohazardous medical waste. In fact, their average is 8 times less than the next highest amount produced by home health agencies and 32 times less than the amount produced by physicians' offices and clinics. The impact of this rule upon dentists' offices, and other small quantity generators, may be the greatest on a per pound basis. This phenomenon is directly related to the industry's pricing scheme and the small quantity of biohazardous medical waste produced. Treatment costs, for instance, expressed as equivalent costs per pound, range from a high of $19.81 for dentists' offices to a low of 67¢ for hospitals.

Except for hospitals, and other large quantity generators that can negotiate off-site treatment on a per pound basis, most nonhospital generators pay a per container charge for pickup to have their biohazardous medical waste treated off-site. Furthermore, some generators may pay a transportation surcharge if the treater, or a 3rd-party transporter, must transport their biohazardous medical waste a long distance to their treatment facility.

C. COST-EFFECTIVE ALTERNATIVES

This rule does not mandate a specific treatment methodology. Moreover, the proposed rule allows new alternative treatment technologies to enter the Arizona market. Therefore, generators can choose the best treatment options for their business. This would include both on-site and off-site treatment options. For some generators, 1 option for reducing business costs may be to segregate non-biohazardous medical waste from biohazardous medical waste. Increased market competition in the future may help to reduce costs for some of these generators and to help maintain a market equilibrium for others.

For some small quantity generators, the mail-back kit, or an on-site system that encapsulates medical sharps, may be the most economical method of treating biohazardous medical waste. For other generators, it may mean fewer pickups by a treater, or a combination of fewer pickups and purchasing larger containers. It may also mean some generators will have to construct a larger storage area. For yet other generators, it may mean purchasing an autoclave, or another comparable type of equipment to treat their biohazardous medical waste. Finally, for other generators, a cost-effective alternative may be to use equipment already on-site to treat their biohazardous medical waste. For example, the autoclave could serve a dual purpose for sterilizing medical instruments and supplies and for treating biohazardous medical waste. For generators that decide to purchase a benchtop autoclave, the cost will range from $1,500 to $5,000. Even if the economic impacts of this rule on generators are relatively minimal, any increased costs of doing business by the generators probably will be passed on to consumers of healthcare services.

D. REQUEST FOR DATA

Table 1 contains a summary of findings from the generator survey. If you would like to comment on these findings or obtain a copy of the preliminary EIS from the Department, please contact David Lillie at (602) 207-4436. The preliminary EIS contains an explanation of survey findings, methodology, reliability, and assumptions. The Department will review and evaluate all comments and data received prior to completing the final EIS and the adoption of this rule.

Table 1. Hospital and Nonhospital Biohazardous Medical Waste Generators: Summary of Survey Findings, 1995

Category of Generator a/	Estimated Number of Facilities b/	Estimated Sample Size (%)	Average Amount of Waste (lbs. per mo.) c/	Medical Sharps (% of waste)	Average Cost to Treat ($ per month)	Average Cost to Treat ($ per pound)
Hospitals	110	44.5	12,298	18	2,590	.67
Physicians	4,185	2.8	128	43	160	4.79
Dentists	1,632	1.9	4	65	35	19.81
Nursing	571	4.4	61	40	88	6.05

Vets	362	1.4	56	61	43	1.89
Funeral	156	15.0	101	1	146	1.98
Laboratories	140	5.0	299	21	147	1.24
Home	134	9.7	32	79	50	4.07

Source: Number of facilities by generator category were derived from state data bases and data from the U.S. Department of Commerce. Averages reported in this table represent weighted averages.

a/ The universe of generators includes 2 groups: hospital generators and nonhospital generators. Nonhospital generators include the following: physicians' offices and clinics, dentists' offices, nursing and long-term care facilities, veterinarians, funeral homes/ crematories, laboratories, and home health agencies.

b/ Nearly 80% of the generators would be classified as small businesses according to survey inferences.

c/ These generators produce an estimated 22.2 million pounds of biohazardous medical waste annually. Hospitals produce 2-thirds of this amount, or 14.7 million pounds; nonhospital generators produce the remaining 7.5 million pounds.

7. **The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business and consumer impact statement:**

Name: David Lillie

Address: Department of Environmental Quality
3303 North Central Avenue, Eighth Floor
Phoenix, Arizona 85012-2809

Telephone: (602) 207-4436 or (800) 234-5677, ext. 4436 (Arizona only)

Fax: (602) 207-2251

8. **The time, place and nature of the proceedings for the adoption, amendment or repeal of the rule, or, if no proceeding is scheduled, where, when and how persons may request an oral proceeding on the proposed rule:**

Persons interested in submitting written comments on the proposed rules should mail or fax them to Katheryn A. Cross, identified in question 3, above no later than 5 p.m. on June 28, 1996.

A series of public hearings have been scheduled to discuss the proposed rule and to receive public comments. They are scheduled for the following times and locations:

Date: June 10, 1996

Time: 1 p.m.

Location: Flagstaff City Council Chambers
211 West Aspen Avenue
Flagstaff, Arizona

Date: June 12, 1996

Time: 1 p.m.

Location: State Office Building
400 West Congress
Room #5, South Building
Tucson, Arizona

Date: June 13, 1996

Time: 1 p.m.

Location: ADEQ Public Meeting Room
3033 North Central Avenue
Phoenix, Arizona

The ADEQ is committed to complying with the Americans with Disabilities Act. If any individual with a disability needs any type of accommodation, please call (602) 207-4795 for special accommodations pursuant to the Americans with Disabilities Act. Persons interested in presenting verbal comments, submitting written comments, or obtaining more information on the proposed rules may do so at these meetings. The ADEQ will respond to all issues in the preamble accompanying the final rules.

9. **Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:**
Not applicable.

10. **Incorporation by reference and their location in the rules:**
Not applicable.

11. **The full text of the rules follows:**

TITLE 18. ENVIRONMENTAL QUALITY

CHAPTER 13. DEPARTMENT OF ENVIRONMENTAL QUALITY WASTE MANAGEMENT

ARTICLE 14. MEDICAL WASTE

ARTICLE 14. MEDICAL WASTE

R18-13-1401. Definitions

In addition to the definitions in A.R.S. § 49-701, the following definitions shall apply in this Article:

1. "Approved facility" means a solid waste facility which has received facility plan approval from the Department in accordance with A.R.S. Title 49, Chapter 4, Article 4 and the rules promulgated under this Chapter.
2. "Biohazardous medical waste" means medical waste, as defined in A.R.S. § 49-701, including any of the following. Medical waste which does not fall within the definition for biohazardous waste as set forth herein, is subject to regulation as solid or hazardous waste. Biohazardous medical waste is described by 1 or more of the following:
   a. Cultures and stocks: Cultures and stocks of infectious agents and associated biologicals, including cultures from medical and pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, wastes from the production of biologicals, discarded live and attenuated vaccines, and culture dishes and devices used to transfer, inoculate, and mix cultures.
   b. Waste human blood and blood products: Discarded waste human blood and blood components, such as serum and plasma, and material containing free-flowing blood and blood components.
   c. Pathological wastes: Human pathological wastes, including tissues, organs, and body parts excluding hair and fingernails, that are removed during autopsy or other medical procedures. Pathological waste does not include body fluids, except blood and blood products as previously described.
   d. Medical sharps: Discarded sharps, whether used or unused, in animal or human patient care or treatment or in medical, research or industrial laboratories, including hypodermic needles, syringes, pasteur pipettes, glass contaminated with blood or specimen, and scalpel blades.
   e. Research animal waste: Contaminated animal carcasses, body parts, and bedding of animals that were exposed to infectious agents during research, production of biologicals, or testing of pharmaceuticals.
   f. Isolation waste: Biological waste and discarded materials contaminated with blood, excretion, or exudates, or secretions from humans who are isolated to protect others from highly virulent diseases. Highly virulent diseases are those derived from Class IV etiologic agents as defined by the Centers for Disease Control in Atlanta, Georgia.
3. "Biohazardous medical waste transporter" or "transporter" means a person engaged in the transportation of biohazardous medical waste.
4. "Biologicals" means preparations made from living organisms or their products, including vaccines, cultures, or other biological products intended for use in diagnos-

ing, immunizing or treating humans or animals or in research pertaining to such activities.

5. "Blood and blood products" means discarded human blood and blood products derived from blood or blood components.
6. "Body fluids" means any substance which emanates or derives from the human body including: bulk laboratory specimens of blood, tissue, semen, vaginal secretions, cerebro-spinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, and amniotic fluid. Feces, nasal secretions, sputum, sweat, tears, urine, or vomitus are "body fluids" only if they contain visible blood.
7. "Chemotherapy waste" means any discarded material which has come in contact with an agent that kills or prevents the reproduction of malignant cells.
8. "Collection" means pick-up by transporters for transport away from the facility. Collection does not include internal building pick-up by a janitorial service.
9. "Contaminate" means to soil, stain, or infect by the transfer of blood or other matter that may contain infectious agents.
10. "Discarded drug" means any prescription drug, over-the-counter medicine, or controlled substance which is used in the diagnosis, treatment, or immunization of a human being or animal, and which is placed in a disposal receptacle for collection, but does not include hazardous waste or controlled substances regulated by the United States Drug Enforcement Agency.
11. "Facility plan" has the meaning given to it in A.R.S. § 49-701, and includes a new facility plan, an initial facility plan, all plan modifications, a closure plan, or a post-closure plan.
12. "Generator" means any person, by site, whose act or process produces regulated medical waste or whose act 1st causes a regulated medical waste to become subject to regulation. In the case where more than 1 person are located in the same building, each individual business entity is a separate generator for the purposes of this part.
13. "Improperly Dispose" or "Improper Disposal" means the discharge, deposit, injection, dumping, spilling, leaking, or placing of biohazardous medical waste into or on any land or waters of the state so that the biohazardous medical waste or any of its constituents may enter the environment or be emitted into the air, or discharged into any waters of the state, including groundwater.
14. "Infectious agent" means any type of microorganism, bacteria, mold, parasite, or virus which normally causes, or significantly contributes to the cause of, increased morbidity or mortality of human beings.
15. "Manifest" means the biohazardous medical waste manifest or written documentation which contains the name, address, and telephone number of the generator and transporter; the quantity of biohazardous medical waste collected and delivered; and the date the biohazardous medical waste is collected, delivered, and treated.
16. "Medical sharps container" means a container that is rigid, puncture resistant, leak proof, and cannot be reopened without great difficulty.
17. "Medical waste treatment facility" or "treatment facility" is a solid waste facility approved by the Department to accept and treat biohazardous medical waste generated off-site.
18. "Non-biohazardous medical waste" means medical waste not meeting the definition of biohazardous medical waste. Medical waste which does not fall within the definition for biohazardous medical waste is solid waste, and subject to regulation under A.R.S. Title 49, Article 4.
19. "Non-putrescible state" means to maintain putrescible biohazardous medical waste in order to control the dispersion of foul-smelling odors from material that is capable of being decomposed by microorganisms.
20. "Off-site" means any site that does not meet the definition of on-site as defined in A.R.S. § 49-701(19).
21. "Packaging" means the use of a container or a practice as described in R18-13-1407.
22. "Regulated hazardous waste" has that meaning given it in A.R.S. § 49-921(5).
23. "Secure" means to lock or otherwise restrict access to authorized personnel.
24. "Spill" means any release of biohazardous medical waste that is neither expected nor intended.
25. "Store" or "storage" means, in addition to the meaning given it in A.R.S. § 49-701(29), temporary holding or aggregation in a container awaiting collection, or the aggregation of biohazardous medical waste at a designated accumulation area, at the end of which the waste is transported, treated, disposed of, or stored elsewhere.
26. "Transport" means the movement of biohazardous medical waste from the point of generation to an intermediate approved storage facility or to an approved treatment facility. A biohazardous transporter collects for the purpose of transportation to a treatment facility.
27. "Transportation management plan" means the written plan consisting of procedures used to minimize the exposure of employees to biohazardous medical waste throughout the process of transporting and handling, and emergency procedures used for handling spills or accidents.
28. "Treat" or "treatment" means achievement of any 1 of the treatment standards as demonstrated pursuant to R18-13-1412(B). A "treater" means a person who treats biohazardous medical waste.
29. "Treatment certification statement" means the written document described in R18-13-1414.
30. "Universal biohazard symbol" means the symbol design that conforms to the design shown in 29 CFR 1910.1030(g)(1)(i)(B) as amended as of July 1, 1995.
31. "Vehicle dedicated to the transportation of biohazardous medical waste" means a vehicle whose only purpose is to transport solid waste or biohazardous medical waste.
32. "Vehicle not dedicated to the transportation of biohazardous medical waste but which is engaged in commerce" means a vehicle whose primary purpose is not transportation of solid waste or biohazardous medical waste but which is used on a temporary basis for this purpose.

R18-13-1402. Applicability

A. This Article applies to a person who generates, stores, collects, transports, or treats biohazardous medical waste.

B. A generator, except as provided for in R18-13-1403, is responsible for retrieving and treating biohazardous medical waste that has been improperly disposed.

C. A treater who treats waste generated on-site and who accepts exempt waste described in R18-13-1403(A)(1) does not trigger a requirement for facility plan approval absent other regulatory requirements.

D. A person who manages biohazardous medical waste which also contains radioactive materials, as defined in R12-1-102, shall manage that waste in a manner that does not violate the provisions of 12 A.A.C. 1. A person shall manage the waste in accordance with this Article after the radioactive component has decayed in storage as provided in 12 A.A.C. 1. A person

shall package the waste to conform to the requirements of this Article unless the requirements of 12 A.A.C. 1 are more restrictive.

E. Biohazardous medical waste which is treated by a method meeting the performance standards described in R18-13-1412 and which is set out by a treatment facility for collection and disposal at a municipal landfill shall be handled in accordance with this Section and solid waste requirements set forth under A.R.S. Title 49, Chapter 4 and the provisions of 18 A.A.C. 8.

R18-13-1403. Exemptions

A. The following are exempt from the requirements of this Article:
   1. A household generator residing in a private, public, or semi-public residence who generates biohazardous medical waste in the administration of self-care, or the agent of the household generator who administers the medical care. A facility licensed by the Department of Health Services does not qualify for this exemption.
   2. Human corpses, remains, and anatomical parts that are intended for interment or cremation.
   3. Source, special nuclear or by-product material as defined by the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2011 et. seq. (See R18-8-261(C)).
   4. Medical sharps, unused but not discarded, which are returned to the manufacturer via the U.S. Postal Service.
   5. Biohazardous medical waste deposited in a sanitary sewer system if performed under authority of the local waste water treatment facility in compliance with federal and local permit conditions pursuant to 40 CFR 460.12, as amended as of July 1, 1995.
   6. Hazardous waste subject to regulation under A.R.S. Title 49, Chapter 5 which is not conditionally exempt from hazardous waste requirements.

B. A multi-purpose vehicle used by health personnel in the conduct of routine business shall be exempt from the requirements of this Article if all of the following are met:
   1. The biohazardous medical waste is packaged as described in R18-13-1407.
   2. The vehicle is equipped with compartments or other barriers, and biohazardous medical waste is contained within the compartment in a separate sealed rigid container.
   3. The container is decontaminated weekly and when it shows visible signs of contamination.
   4. The biohazardous medical waste is transported to a treatment facility for treatment.

C. A person who transports biohazardous medical waste between multiple properties owned or operated by the same owner or governmental entity shall be subject to the packaging requirements described in R18-13-1407 of this Article. Receipt of biohazardous medical waste transported from 1 commonly owned or operated facility to another does not render the receiving facility a public facility as defined in this Article.

R18-13-1404. Transition

A. An on-site incinerator, or on-site sterilization unit which is brought into operation on or after the effective date of this Article, shall be subject to the requirements of R18-13-1421. An on-site alternative medical waste treatment unit in operation on the effective date of this Article shall come into compliance with the provisions of R18-13-1421 within 180 days after the effective date of this Article.

B. A medical waste treatment facility in operation on the effective date of this Article is subject to the requirements of R18-13-1413. Within 180 days after the effective date of this Article, the facility shall come into compliance with the provisions of R18-13-1421.

C. A facility which has obtained approval as a solid waste facility pursuant to A.R.S. § 49-762 before the effective date of this Section, or a transfer facility may continue to treat or transfer biohazardous medical waste if the facility submits, within 90 days after the effective date of this Article, an updated plan to the Department demonstrating compliance with R18-13-1420. The addition of a refrigeration unit is not considered a substantial plan change by the Department.

R18-13-1405. Generators

A. A generator of biohazardous medical waste may either treat waste on-site, or transport waste to a treatment facility described in R18-13-1420.

B. A generator who treats biohazardous medical waste or discarded drugs on-site shall comply with R18-13-1412, R18-13-1414, and R18-13-1416 through R18-8-1419 prior to setting the waste out for collection and disposal at a Department approved solid waste processing, recycling, or disposal facility. The generator shall also comply with the provisions of R18-13-1421.

C. A generator who transports biohazardous medical waste or discarded drugs to a treatment facility for treatment shall comply with R18-13-1406 through 1408, R18-13-1411, and R18-13-1417.

R18-13-1406. Segregation

A generator of biohazardous medical waste may segregate biohazardous medical waste from non-biohazardous medical waste. Commingled biohazardous and non-biohazardous medical waste is regulated as biohazardous medical waste in accordance with the provisions of this Article.

R18-13-1407. Packaging

A. A generator shall package biohazardous medical waste in either of the following:
   1. A red biohazard bag which meets the standards set forth in 49 CFR 106, as amended as of July 1, 1995, for a classified strength of at least 200 pound test and be class DOT-12A80 or DOT-12A50. The bag shall be tied to prevent leakage of contents or breakage during storage, handling, or transport.
   2. A reusable container or bag which bears the universal biohazard symbol and which satisfies all of the following:
      a. The container shall be leakproof on all sides and bottom, closed with a fitted lid, and constructed of smooth, easily cleanable materials that are impervious to liquids and resistant to corrosion by disinfecting agents.
      b. All disposable packaging and liners shall be managed as regulated medical waste and shall not be reused.
      c. Any container used for the storage or transport of regulated medical waste and designated for reuse once emptied must be decontaminated unless the inner surfaces of the container have been protected from contamination by disposable liners, bags, or other devices removed with the waste. Decontamination means agitation to remove visible soil combined with 1 of the following:
         i. Exposure to hot water of at least 180° F. for a minimum of 15 seconds;
         ii. Exposure to an EPA-approved chemical disinfectant in accordance with established protocols and regulations;
         iii. Any other manner that the Department determines is acceptable, provided that the determination of acceptability is made in advance of decontamina-

tion.

d. Any container used for the storage or transport of regulated medical waste which is not capable of being decontaminated in accordance with subsection (A)(2)(c) above, shall be handled as biohazardous medical waste in accordance with this Article.

B. Encapsulation and subsequent disposal as municipal solid waste may be used if the agent used to solidify and encase the contents meets the treatment standards of R18-13-1412. Encapsulated medical sharps shall be rendered incapable of being reused before encapsulation.

C. Medical sharps shall be packaged as described in R18-13-1416.

R18-13-1408. Storage

A. A generator may place a container of biohazardous medical waste alongside a container of general solid waste if the biohazardous medical waste is not allowed to co-mingle with the solid waste.

B. A generator may store biohazardous medical waste on-site for no longer than 90 days from the date waste is placed in a container for collection. Storage of biohazardous medical waste for longer than 90 days requires facility plan approval pursuant to A.R.S. § 49-762. The maximum storage time may be that period set forth in the facility approval plan from the Department.

C. Beginning at the time waste is set out for collection, a generator who stores biohazardous medical waste shall comply with all of the following:

1. The generator may keep putrescent biohazardous medical waste unrefrigerated provided that it does not create a nuisance. Putrescent biohazardous medical waste may be kept longer than 7 days provided that it is refrigerated at 40° F. or less. Biohazardous medical waste shall not be kept for longer than 90 days without facility plan approval.
2. The generator shall protect biohazardous medical waste from contact with water, precipitation, wind, or animals. The waste shall not provide a breeding place or a food source for insects or rodents.
3. The generator shall store a container of biohazardous medical waste in an area away from general traffic flow patterns, and shall restrict access or contact to authorized persons.
4. The generator shall not use reusable containers for any purpose other than the storage of biohazardous medical waste.
5. The generator shall not use biohazardous medical waste storage areas to store substances for human consumption or for medical supplies.
6. The generator shall keep storage areas free of contamination.
7. The generator shall display the universal biohazard hazard symbol and shall post warning signs worded as follows: in English: "CAUTION -- BIOHAZARDOUS WASTE STORAGE AREA -- UNAUTHORIZED PERSONS KEEP OUT," and in Spanish, "PRECAUCION -- ZONA DE ALMACENAMIENTO DE DESPERDICIOS BIOLOGICOS PELIGROSOS -- PROHIBIDA LA ENTRADA A PERSONAS NO AUTORIZADAS."
8. The generator shall handle spills occurring in storage areas in accordance with R18-8-1407(A)(2)(c).
9. The generator shall minimize objectionable odors and off site migration. Where a generator complies with subsections (C)(1) through (8) above, and the facility is unable to control the odor from its stored waste and the odor constitutes a nuisance pursuant to A.R.S. § 49-141, the Department may require more frequent removal.

D. A medical waste treatment facility shall store waste in accordance with subsection (C) above.

R18-13-1409. Transportation

A. A person who transports biohazardous medical waste shall comply with all of the following:

1. Accept only biohazardous medical waste packaged in accordance with R18-13-1407.
2. Accept only biohazardous medical waste accompanied by a manifest described in R18-8-1411.
3. Deliver biohazardous medical waste to a treatment facility within 24 hours of collection or refrigerate the waste at 40° F. or less until delivery.
4. Not hold biohazardous medical waste longer than 4 days in a refrigerated vehicle unless the vehicle is parked at a Department-approved facility.
5. Deliver the biohazardous medical waste to a Department-approved facility.
6. Maintain in each vehicle a copy of the biohazardous medical waste transportation management plan.
7. Prior to reaching a treatment facility, not unload, reload, or transfer the biohazardous waste to another vehicle at any location other than a Department-approved facility, except in emergency situations. However, combination vehicles may be coupled and uncoupled to another cargo vehicle or truck trailer so long as the biohazardous medical waste is not removed from the cargo compartment.

B. A person who transports biohazardous medical waste in a vehicle dedicated to biohazardous medical waste collection shall possess a permit, license, or approval where required by a local health department, environmental agency, or other governmental agency with jurisdiction. In addition, a transporter shall meet all the following vehicle requirements:

1. For a cargo vehicle:
   a. Security which limits access to persons who are specifically designated to handle such waste.
   b. A fully enclosed, leak-proof, cargo-carrying body, such as a cargo compartment or box trailer.
   c. A cargo compartment consisting of a floor and sides which are made of an impervious, nonporous material.
2. For all vehicles, the vehicle shall meet all of the following operation standards:
   a. Securely close all discharge openings during operation of the vehicle.
   b. Decontaminate the vehicle as described in R18-13-1407(A)(2)(c) when it shows signs of contamination.
   c. Lock the cargo compartment at all times when biohazardous medical waste is present except during loading or unloading of such waste.

C. A person who operates a vehicle which is not dedicated to waste collection but which is engaged in commerce shall comply with subsection (A) and with R18-13-1409. In addition, the vehicle and cargo compartment shall be cleaned in accordance with R18-13-1407(A)(2)(c) weekly, when it shows signs of contamination, and upon completion of the job.

D. The requirements of this Section do not apply to an emergency rescue vehicle, an ambulance, or a blood service collection vehicle if medical sharps are packaged in accordance with R18-8-1409. For these vehicles, the biohazardous medical waste shall be transported to a central collection facility which is considered to be the point of generation.

E. A generator, including a transporter who initiates the tracking form, who exports regulated medical waste to another state or

foreign country for treatment and destruction, or disposal, shall request that the destination facility provide written confirmation that the waste was received. If the generator has not received that confirmation from the destination facility within 45 days from the date of acceptance of the waste by the first transporter, the generator shall submit an exception report in accordance with R18-13-1411.

R18-13-1410. Transporter Spills; Accidents

A. In the event of a spill or vehicle accident, a transporter shall manage any spill in accordance with local, state, and federal rules governing such an occurrence.

B. Within 2 business days after spill clean up, a transporter shall notify the Department, the generator, and the local health department of the emergency situation.

C. A transporter shall be responsible for cleaning up any accident or spill which occurs while the waste is in the transporter's possession.

D. Each vehicle shall carry spill containment and clean-up kits containing all of the following:
1. Material designed to absorb spilled liquids in an amount sufficient to absorb 10 gallons.
2. One gallon, or concentrated liquid or powder with the appropriate diluent sufficient to make 1 gallon of a chemical disinfectant.
3. 10 red biohazardous bags.
4. One set of impermeable and disposable overalls, gloves, boots, caps, protective eyewear, and tape. Overalls, boots, and caps shall be made of material which semi-encapsulates the wearer and is highly resistant to liquids.
5. A first-aid kit, fire extinguisher, boundary tape, lights, and other appropriate safety equipment.

R18-13-1411. Manifest

A. A generator of biohazardous medical waste shall submit the manifest as described in this Section to a transporter. Each person who takes physical possession of the biohazardous medical waste shall provide information on the manifest regarding that possession. The completed manifest shall include all of the following information:
1. The name, address, telephone number, and signature of the following persons:
   a. The generator,
   b. The transporter,
   c. The authorized representative of the Department-approved facility receiving the biohazardous medical waste,
   d. The authorized representative of the transfer station.
2. The quantity of biohazardous medical waste collected by weight, volume, or number of containers.
3. The quantity of biohazardous medical waste delivered.
4. The following dates:
   a. The date the biohazardous medical waste is collected,
   b. The date the biohazardous medical waste is delivered to the Department approved receiving facility or transfer station,
   c. The date the biohazardous medical waste is treated.

B. Upon accepting biohazardous medical waste, a transporter shall sign and date the manifest and give the generator a signed copy. A transporter shall keep a copy of the signed manifest for 6 months from date of receipt of the waste. The manifest shall accompany biohazardous medical waste until the waste is treated.

C. Upon accepting biohazardous medical waste, a treater or transfer facility operator shall sign and date the manifest and give a copy to the transporter, send a copy to the generator and any transfer facility, and retain a copy for 6 months.

D. A person may consolidate manifests as long as the consolidated manifest meets the requirements of this Section.

E. A generator who does not receive a copy of the manifest or documentation signed by the operator of an approved treatment facility or transfer facility within 40 calendar days of the date the transporter accepted the biohazardous medical waste shall immediately contact the transporter to determine the status of the shipment. In addition, the generator shall notify the Department in writing if, within 55 days of the date the transporter accepted the waste, no signed manifest has been received from the approved treatment facility or any transfer facility. This Departmental notification shall be in addition to the efforts of the generator to trace the shipment. The Departmental notification shall include all of the following:
1. Name and address of the generator and transporter;
2. Date the waste was originally accepted by the transporter;
3. The quantity of biohazardous medical waste, in number of containers or pounds;
4. A cover letter describing the efforts taken by the generator to resolve the problem;

F. The Department may approve other tracking methods, documentation, or consolidation of manifests that it determines are substantially in compliance with the requirements of this Section.

R18-13-1412. Treatment Standards, Quantification Of Microbial Inactivation And Efficacy Testing Protocols

A. Biohazardous medical waste treated by 1 of the following methods is solid waste:
1. Incineration, which meets the treatment standards set forth in this Section;
2. Steam sterilization or other sterilization, which meets the treatment standards set forth in this Section;
3. An alternative medical waste treatment method which meets the treatment standards set forth in this Section.

B. The treater shall not use compaction as a treatment method for biohazardous medical waste. A treater may use grinding in combination with another treatment method described in this Section if it is conducted in a closed system to prevent exposure to humans and the environment. Where grinding is used for medical sharps, such grinding shall render the medical sharps incapable of being reused.

C. The treater shall ensure that treatment achieves 1 or more of the following treatment standards:
1. Inactivation is required to be demonstrated for vegetative bacteria, fungi, lipophilic/hydrophilic viruses, and mycobacteria at a 6 Log 10 reduction or greater. Inactivation is required to be demonstrated of parasites at a 2 Log 10 reduction or greater.
2. Inactivation is required to be demonstrated of *B. stearothermophilus* spores or *B. subtilis* spores at a 4 Log 10 reduction or greater.

D. The treater shall use 1 or more of the following representative biological indicators to demonstrate treatment efficacy:
1. One or more of the following representative microorganisms from each microbial group shall be used to determine if microbial inactivation requirements are met:
   a. Vegetative bacteria:
      i. Staphylococcus aureus (ATCC 6538),
      ii. Pseudomonas aeruginosa (ATCC 15442),
   b. Fungi:
      i. Candida albicans (ATCC 18804),
      ii. Penicillium chrysogenum (ATCC 24791),
      iii. Aspergillus niger
   c. Viruses: MS-2 Bacteriophage (ATCC 15597-B1)

d. Parasites:
i. Cryptosporidium spp. oocysts,
ii. Giardia spp. cysts
e. Mycobacteria:
i. Mycobacterium terrae,
ii. Mycobacterium phlei,
iii. Mycobacterium bovis (BCG) (ATCC 35743)

2. Spores from 1 of the following bacterial species shall be used for efficacy evaluation of chemical, thermal, and irradiation treatment systems:
a. B. stearothermophilus (ATCC 7953),
b. B. subtilis (ATCC 19659)

E. The treater shall quantify microbial inactivation as follows:

1. Microbial inactivation, or "kill" efficacy is equated to "Log^{10} Kill" which is defined as the difference between the logarithms of the number of viable test microorganisms before and after treatment. This definition is equated as:

$Log^{10}Kill = Log^{10}(cfu/g\ "I") - Log^{10}(cfu/g\ "R")$

where:

$Log^{10}Kill$ is equivalent to the term Log^{10} reduction;

"I" is the number of viable test microorganisms introduced into the treatment unit;

"R" is the number of viable test microorganisms recovered from the treatment unit; and

"cfu/g" are colony forming units per gram of waste solids.

2. For those treatment processes that can maintain the integrity of the biological indicator carrier of the desired microbiological test strain, biological indicators of the required strain, and concentration may be used to demonstrate microbial inactivation. Quantification is evaluated by growth or no growth of the cultured biological indicator.

3. For those treatment mechanisms that cannot ensure or provide integrity of the biological indicator, quantitative measurement of microbial inactivation requires a 2 step approach: Step 1 "Control" and Step 2 "Test". The purpose of Step 1 is to account for the reduction of test microorganisms due to loss by dilution or physical entrapment.
a. Step 1:
i. Use microbial cultures of a predetermined concentration necessary to ensure a sufficient microbial recovery at the end of this step.
ii. Add suspension to a standardized medical waste load that is to be processed under normal operating conditions without the addition of the treatment agent (i.e., heat, chemicals).
iii. Collect and wash waste samples after processing to recover the biological indicator organisms in the sample.
iv. Plate the recovered microorganism suspensions to quantify microbial recovery. The number of viable microorganisms recovered serves as a baseline quantity for comparison to the number of recovered microorganisms from wastes processed with the treatment agent.
v. The required number of recovered viable indicator microorganisms from Step 1 must be equal to or greater than the number of microorganisms required to demonstrate the prescribed Log reduction, either a 6 Log^{10} reduction for vegetative microorganisms or a 4 Log^{10} reduction for bacterial spores. This can be defined by the following equation:

$Log^{10}RC = Log^{10}IC - Log^{10}NR$

or

$Log^{10}NR = Log^{10}IC - Log^{10}RC$

where:

$Log^{10}RC$ is greater than 6 for vegetative microorganisms and greater than 4 for bacterial spores and where:

$Log^{10}RC$ is the number of viable "Control" microorganisms in colony forming units per gram of waste solids recovered in the non-treated processed waste residue;

$Log^{10}IC$ is the number of viable "Control" microorganisms in colony forming units per gram of waste solids introduced into the treatment unit;

$Log^{10}NR$ is the number of "Control" microorganisms in colony forming units per gram of waste solids which were not recovered in the non-treated processed waste residue. $Log^{10}NR$ represents an accountability factor for microbial loss.

b. Step 2:
i. Use microbial cultures of the same concentration as in Step 1.
ii. Add suspension to the standardized medical waste load that is to be processed under normal operating conditions with the addition of the treatment agent.
iii. Collect and wash waste samples after processing to recover the biological indicator organisms in the sample.
iv. Plate recovered microorganism suspensions to quantify microbial recovery.
v. From data collected from Step 1 and Step 2, the level of microbial inactivation, "Log10 Kill", is calculated by employing the following equation:

$Log^{10}Kill = Log^{10}IT - Log^{10}NR - Log^{10}RT$

where:

$Log^{10}Kill$ is equivalent to the term Log^{10} reduction; $Log^{10}IT$ is the number of viable "Test" microorganisms in colony forming units per gram of waste solids introduced into the treatment unit, $Log^{10}IT = Log^{10}IC$;

$Log^{10}NR$ is the number of "Control" microorganisms in colony forming units per gram of waste solids which were not recovered in the non-treated processed waste residue;

$Log^{10}RT$ is the number of viable "Test" microorganisms in colony forming units per gram of waste solids recovered in treated processed waste residue.

F. Any methodology employed to determine treatment efficacy of the technology shall assure required microbial inactivation and shall assure that the protocols are congruent with the treatment method. Acceptable demonstration of compliance is required. Acceptable demonstration is submitted to the Department from a laboratory licensed by the Department of Health Services.

R18-13-1413. Medical Waste Treatment Facility: Plan Approval Requirement

A. The treater shall obtain solid waste facility plan approval pursuant to A.R.S. § 49-762. Plan approval is granted where the applicant successfully demonstrates compliance with this Chapter.

B. The treater shall have both solid waste plan approval from the Department. In addition, a treater who uses incineration technology shall have an air quality permit pursuant to A.R.S. Title 49. The air quality permit shall be granted from the Department or the local environmental agency having jurisdiction. The facility shall be permitted in accordance with A.R.S. §§ 49-426 or 49-480 and the rules or ordinances promulgated thereunder.

R18-13-1414. Treatment Certification Statement

A. After treating biohazardous medical waste, the treater shall prepare and sign a certification statement which certifies that the waste has been treated in accordance with R18-13-1412. The certification statement shall include the name, address, telephone number, and the signature of the person or facility responsible for treatment and the date the waste was treated. One copy shall be sent to the generator and 1 copy kept on file at the treatment facility and shall be made available to the landfill operator upon request.

B. The on-site treater shall provide a treatment certification statement to transporters and disposers if requested.

R18-13-1415. Disposal

A. Biohazardous medical waste treated by a method which achieves the treatment standards described in R18-13-1412 may be sent to a Department-approved landfill or a recycling facility.

B. In the event of a public health emergency and with the written approval of the Department, untreated biohazardous medical waste may be placed in an approved municipal solid waste landfill if accepted by the landfill operator.

R18-13-1416. Medical Sharps

A. The generator shall segregate medical sharps from other biohazardous medical waste and place medical sharps in a medical sharps container. A medical sharps container may be mixed with other biohazardous medical waste.

B. The generator shall handle medical sharps in 1 of the following ways:

1. Treat medical sharps as described in R18-13-1412 and render them incapable of being reused. A generator who places treated medical sharps in a sharps container without an encapsulating agent does not satisfy the requirement to render them incapable of being reused.
2. Properly package the medical sharps and send them to a treatment facility via a postal mail-back system. An Arizona treatment facility shall render medical sharps incapable of being reused.

R18-13-1417. Mixed Biohazardous And Hazardous Waste.

A. Medical waste as defined in R18-13-1401 which also contains radioactive materials as defined in R12-1-102, shall be managed in a manner that does not violate the provisions of 12 A.A.C. 1. Such waste shall be managed in accordance with the provisions of this Article after the radioactive component has decayed in storage as provided in 12 A.A.C. 1. Packaging for such waste shall conform to the requirements of this Article unless the requirements of 12 A.A.C. 1 are more stringent.

B. Biohazardous medical waste and regulated hazardous waste, when combined, is hazardous waste and is subject to regulation as specified in the statutes and regulations applicable to hazardous waste.

C. Biohazardous medical waste and radioactive waste, when combined, is radioactive waste and is subject to regulation as specified in statutes and regulations applicable to radioactive waste.

D. Biohazardous medical waste, hazardous waste, and radioactive waste, when combined, is radioactive mixed waste and is subject to regulation as specified in statutes and regulations applicable to hazardous waste and radioactive waste.

E. A mixture of biohazardous medical waste and radioactive materials may be returned without a medical waste manifest if it is shipped directly to the supplier of the radioactive materials for decay in storage. In such a case, the supplier of the radioactive materials is considered the generator for purposes of this Article. The supplier shall be responsible for assuring that the biological hazard is treated after the radioactive component has decayed to background. If the biohazardous waste is released for management of the biological hazard, all the provisions of this Article shall be followed. A user of radioactive materials returning such mixtures to the supplier shall maintain records indicating the facility to which the waste was returned. Containers shall bear the name and address of the supplier. These exemptions do not release these materials from manifests required by other federal, state, or local regulations.

R18-13-1418. Discarded Drugs

A. Discarded drugs not returned to the manufacturer shall be destroyed by any method which prohibits the drug's use. Where federal or state law prescribes the destruction of discarded drugs that law shall be followed.

B. Discarded drugs may be flushed down a sanitary sewer if performed under authority of the local waste water treatment facility in compliance with federal and local permit conditions pursuant to 40 CFR 460.12 as amended July 1, 1995. Liquid drugs shall be diluted to a non-therapeutic dosage.

R18-13-1419. Body Parts

After initial treatment a treater shall further process recognizable human tissue, organs, body parts, and infected animals to render such waste nonrecognizable if a treatment method other than incineration is used.

R18-13-1420. Medical Waste Treatment Facility: Design and Operational Requirements

A. Any facility that is required to obtain plan approval under A.R.S. § 49-762 shall obtain plan approval from the Department prior to storing, transporting, transferring, treating, or disposing of biohazardous medical waste. In addition, a transfer facility shall comply with the requirements of subsection (B) and a treatment facility shall comply with the requirements of subsection (C). The approved facility plan shall set forth the maximum storage time biohazardous medical waste shall remain at the facility.

B. In addition to the requirements of subsection (A), a transfer facility may accept biohazardous medical waste if all of the following are met:

1. The facility stores biohazardous medical waste separate from other solid waste.
2. The facility accepts biohazardous medical waste only if it is accompanied by the manifest described in R18-13-1411.
3. The facility accepts biohazardous medical waste only if packaged as described in R18-13-1407. Where a biohazardous medical waste container is damaged or leaking, improperly labeled, or otherwise unacceptable, a transfer facility operator shall do 1 of the following:
   a. Reject the waste and return it to the generator.
   b. Immediately repackage the waste in accordance with

R18-13-1407.

4. The facility stores biohazardous medical waste as described in R18-13-1408 except that biohazardous medical waste kept for longer than 24 hours shall be refrigerated.
5. The facility delivers the biohazardous medical waste to a Department-approved facility.

C. In addition to the requirements of subsection (A), a medical waste treatment facility may accept biohazardous medical waste if all of the following are met:
1. Written operating procedures maintained, including range and mean of time, temperature and pressure, type of biohazardous medical waste accepted and treated, type of container, closure on container, pattern of loading, water content of waste, and maximum load quantity.
2. Biohazardous medical waste is stored as described in R18-13-1408.
3. Treatment standards are achieved as described in R18-13-1412.
4. A management plan is maintained for the handling of hazardous chemicals, radioactive waste, and chemotherapy waste. The plan shall include an operating procedure that provides for scanning biohazardous medical waste with a Geiger counter and handling waste above background level in accordance with provisions of the plan approval. If there is no plan approval, radioactive waste above background level shall be handled in accordance with state and federal law.
5. If or when biohazardous medical waste container is damaged or leaking, improperly labeled, or otherwise unacceptable, a treater shall do 1 of the following:
   a. Reject the waste and return it to the generator.
   b. Accept the waste and transfer it directly from transporting vehicle to treatment processing unit.
   c. Repackage the waste in accordance with R18-8-1407.
6. The treater follows a procedure for treating or disposing of biohazardous medical waste within 24 hours of receipt of the waste or refrigerating immediately at 40° F. or less upon determining that treatment or disposal will not occur within 24 hours. Storage of refrigerated biohazardous medical waste shall not exceed 90 days.
7. The processing area is cleared of waste and decontaminated at the end of every working day unless the facility is approved to process waste on a 24-hour basis. If the facility is approved to process waste on a 24-hour basis, the processing area shall be cleared of waste and decontaminated after every 24 hours of operation.

D. In addition to meeting the requirements of subsection (B) or (C), a person who applies for facility plan approval after the effective date of this Article shall ensure the facility is designed to meet both of the following:
1. Any floor or wall surface in the processing area of the facility which may come into contact with biohazardous medical waste shall be constructed of a smooth, easily cleanable material that is impervious to liquids.
2. The floor surface in the treatment and storage area shall either have a curb of sufficient height to contain spills or shall slope to a drain connected to an approved sanitary sewage system, an approved septic tank system, or a collection device.

E. In addition to the requirements of R18-13-1421, the treater shall ensure the equipment meets the manufacturer's operational requirements for the duration of equipment use. Written records capable of documenting compliance with manufacturer's specifications shall be kept by the treater for the life of the equipment and made available to the Department upon request.

F. In addition, a treater who treats by incineration shall meet both of the following:
1. The incineration method shall reduce the biohazardous medical waste, excluding metallic items, into carbonized or mineralized ash.
2. Ash resulting from the incineration of biohazardous medical waste shall be handled as follows:
   a. Tested monthly by the Department to determine whether the ash is hazardous waste pursuant to 40 CFR 261.3. (see R18-8-261(A)).
   b. After 3 consecutive test results which show the ash is nonhazardous pursuant to 40 CFR 261.3 (see R18-261(A)), testing is performed every 6 months.
   c. If incinerator ash is determined by the Department to be hazardous waste, such waste shall be regulated according to the Arizona Hazardous Waste Management Act, A.R.S. § 49-922 and 18 A.A.C. 8, Article 2.
   d. If incinerator ash is determined by the Department to be special waste, such waste shall be regulated according to A.R.S. §§ 49-851 through 49-868 and 18 A.A.C. 8, Article 3.

G. The treater shall maintain recordkeeping of equipment maintenance and operational performance levels for the duration of equipment use. Equipment records shall include the date and result of all equipment calibration and maintenance. Operational performance level recordkeeping shall include duration of time for each treatment cycle as follows:
1. Steam treatment and microwaving treatment records including both:
   a. The temperature and pressure maintained in the treatment unit during each cycle.
   b. The method utilized for confirmation of temperature and pressure.
2. Chemical disinfection treatment records describing the solution used.
3. Incineration treatment records including the temperature maintained in the treatment unit during operation.
4. Such other operating parameters as set forth in the manufacturer's specifications.
5. The method used to confirm effectiveness and the test results.

H. The treater shall make treatment records available for Departmental inspection upon request.

R18-13-1421. Equipment Specifications; Requirements

A. The treater shall maintain written documentation for all of the following:
1. Equipment specifications which identify the proper type of biohazardous medical waste to be treated in the equipment and any design or equipment restrictions.
2. Operating procedures for the equipment which ensure the equipment achieves the standards described in R18-13-1412.
3. Instructions for equipment maintenance, testing, and calibration which ensure the equipment achieves the standards described in R18-13-1412.
4. Training manual for the equipment.

B. The treater shall maintain a written certification that the equipment, when operated properly is capable of achieving the treatment standards set forth in R18-13-1412.